

EPA Registration # 91019-1
Volume 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Ann M. Tillman
Agent for Horizon Valley Generics, Inc.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th Street, NW
Gig Harbor, Washington 98332

JUN 25 2013

Dear Ms. Tillman:

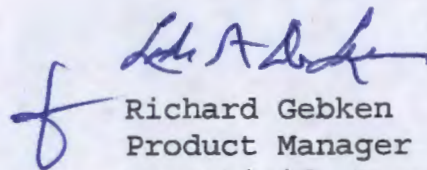
Subject: Amendment-revised basic Confidential Statement
of Formula (CSF)
C668.2 for Dogs
EPA Registration Number 88052-13
Your submission dated May 31, 2013

The basic Confidential Statement of Formula (CSF) dated
May 28, 2013 has been reviewed and is acceptable.

The basic CSF dated May 28, 2013 will supersede the
current basic CSF and replaces the current alternate numbers #1,
#2 and #3.

If you have any questions regarding this action, please
contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,



Richard Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)



ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: June 12, 2013

DP BARCODE No.: 412240

REG. No.: 88052-13

Action Code: 345

Decision No: 479392

Company Name: Horizon Valley Generics, Inc

Name of Product: "C668.2 FOR DOGS"

PC Code: 105402; 129121

FROM: William Herald, Microbiologist / Chemist, NEHA/REHS / Registered Sanitarian
Product Chemistry Team
Technical Review Branch/RD (7505P)

TO: Linda DeLuise / Richard Gebken, RM-10
Insecticide Branch/ RD (7505P)

W Herald
SRB 6/12/13

INTRODUCTION:

With a letter dated May 31, 2013 registrant has submitted an amended Basic CSF (dated 5/28/13) to support the registration of the end use product, "C668.2 FOR DOGS". Registrant desires to revise the CSF to add alternate suppliers for the active ingredients by adding an addendum to the Basic CSF; this change to the Basic is intended to eliminate the current alternate formulations, Alt. Nos. 1-3. Moreover, two sources of the active ingredient were updated to reflect changes in the Reg. Nos. due to transfers to other companies. TRB has been asked to evaluate the said proposed alternate formulation and determine its acceptability.

SUMMARY OF FINDINGS

1. The proposed end use product contains [REDACTED] and [REDACTED] as the active ingredients with the product label claims of 9.8% and 8.8% respectively.
2. The proposed Basic CSF formulation is filled out correctly and completely and is in compliance with PR Notice 91-2. All of the inert ingredients present in the formulation have been approved by the Agency for non-food use only (A. Debesai, 6/11/13).
3. The active and inert ingredients are in compliance with statutory parameters recited in Title 40 CFR § 158.350 (b) (2) and (c).
4. The nominal concentrations of the active ingredients recited in the said amended Basic CSF formulation concurs with the product label claims of nominal concentrations.

CONCLUSIONS:

1. The TRB has reviewed the proposed Basic CSF formulation (dated 5/28/13) and has determined it to be acceptable.
2. The proposed Basic CSF (dated 5/28/13) supersedes the current Basic CSF and replaces the current Alt. Nos. 1-3 CSF formulations.

W. J. Herald 2013

Confidential Statement of Formula may be entitled to confidential treatment

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

June 6, 2013

COURIER DELIVERY

Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202



RE: Horizon Valley Generics, Inc. – C668.2 for Dogs (EPA Reg. No. 88052-13)
Release for Shipment Date

Dear Mr. Gebken,

On behalf of Horizon Valley Generics, Inc., I am notifying you that Horizon Valley Generics, Inc. does not plan to release any of this product (C668.2 for Dogs) for shipment in 2013. As soon as a shipment date is available, I will submit that information to the Agency.

Please feel free to contact me (253-853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Handwritten signature of Ann M. Tillman

Ann M. Tillman
Agent for Horizon Valley Generics, Inc.

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June 6, 2013

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Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202



RE: Horizon Valley Generics, Inc. - C710.0 for Cats (EPA Reg. No. 88052-14)
Release for Shipment Date

Dear Mr. Gebken,

On behalf of Horizon Valley Generics, Inc., I am notifying you that Horizon Valley Generics, Inc. does not plan to release any of this product (C710.0 for Cats) for shipment in 2013. As soon as a shipment date is available, I will submit that information to the Agency.

Please feel free to contact me (253-853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Handwritten signature of Ann M. Tillman

Ann M. Tillman
Agent for Horizon Valley Generics, Inc.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

May 31, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Horizon Valley Generics, Inc.
C668.2 for Dogs (EPA File Symbol 88052-13)
Amendment to Add Additional Sources of Active Ingredient

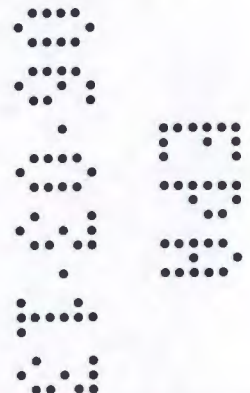
Dear Mr. Gebken,

On behalf of Horizon Valley Generics, Inc. please find the enclosed amendment to the Confidential Statement of Formula (CSF) for C668.2 for Dogs to add additional sources of active ingredient. The new sources are similar to the current sources and are registered for the same uses for which C668.2 for Dogs are registered. The following changes were made:

- The new Basic CSF was prepared in the new format per EPA's November 28, 2011 policy so that CSFs for Alternate Formulations #1, #2, and #3 are combined with the Basic CSF.
- Information for two of the sources of active ingredient was updated to reflect new EPA registration numbers as a result of transfer from another company.
- A registered source of S-methoprene and a registered source of fipronil have been added.

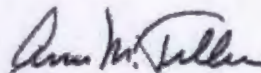
In support of this notification please find the enclosed documents:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Two (2) copies of the amended Basic Formulation CSF dated May 28, 2013
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix
5. Public File Copy of the Data Matrix
6. Letter of Authorization



The enclosed Basic CSF is intended to **REPLACE** the previously approved CSFs for C668.2 for Dogs (Basic and Alternates #1, #2, and #3). Because no data are being submitted with this amendment and no data will need to be reviewed to approve the proposed CSF¹, Horizon Valley Generics, Inc. believes this action qualifies as a Fast Track amendment and is not subject to a Pesticide Registration Service Fee. Please feel free to contact me (253-853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

¹ All generic data cited on the data matrices were reviewed and approved for HVG Fipronil Technical (38052-4).

4/15

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for**

**3 x 0.023 FL. OZ. PACKAGE
3 x 0.045 FL. OZ. PACKAGE
3 x 0.091 FL. OZ. PACKAGE
3 x 0.136 FL. OZ. PACKAGE**

(FRONT PANEL OF CARTON)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))

(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))

(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))

(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-RG

EPA Est. 74720-DEU-01

**ACCEPTED
With COMMENTS
In EPA Letter Dated:**

April 19, 2013

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

88052-13

C668.2 for Dogs - 4-18-2013- 88052-RG

1.

5/15

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

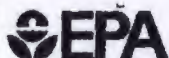
C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively kills and controls fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Horizon Valley Generics Inc./88052-13	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Horizon Valley Generics Inc./C668.2 for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Horizon Valley Generics Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This amendment adds a registered sources of active ingredient to the product CSF.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

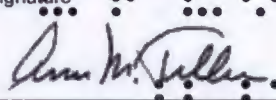
2. Signature 	3. Title Agent	8. Date Application Received Stamp: _____ 11
4. Typed Name Ann M. Tillman	5. Date 5/31/13	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date May 28, 2013			EPA Reg. No./File Symbol 88052-13		Page 1 of 8
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C668.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	48955801	Horizon Valley Generics, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	48955801	Horizon Valley Generics, Inc.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	48955801	Horizon Valley Generics, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	48955801	Horizon Valley Generics, Inc.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	48955801	Horizon Valley Generics, Inc.	OWN	
830.1800	Enforcement Analytical Method	48955802	Horizon Valley Generics, Inc.	OWN	
830.6302	Color	48955803	Horizon Valley Generics, Inc.	OWN	
830.6303	Physical State	48955803	Horizon Valley Generics, Inc.	OWN	
830.6304	Odor	48955803	Horizon Valley Generics, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	48955803	Horizon Valley Generics, Inc.	OWN	
830.6315	Flammability	48955803	Horizon Valley Generics, Inc.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013

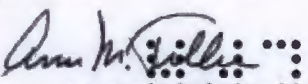
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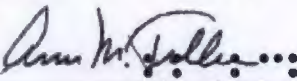
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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C668.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	48955803 48955804	Horizon Valley Generics, Inc.	OWN	Waiver ⁴
830.6317	Storage Stability	48955803 48955804	Horizon Valley Generics, Inc.	OWN	PR-92-5 ⁵
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	48955803 48955804	Horizon Valley Generics, Inc.	OWN	PRN 92-53 ⁵
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	48955803	Horizon Valley Generics, Inc.	OWN	
830.7050	UV/Visible Absorption				Not Required ⁸
830.7100	Viscosity	48955803	Horizon Valley Generics, Inc.	OWN	
830.7200	Melting Point/Melting Range				Not Required ^c
830.7220	Boiling Point/Boiling Range				Not Required ^b
830.7300	Density/Relative Density/Bulk Density	48955803	Horizon Valley Generics, Inc.	OWN	
830.7370	Dissociation Constants in Water				Not Required ⁸
830.7520	Particle size, fiber length, diameter distribution	48955804	Horizon Valley Generics, Inc.	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ⁸
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013

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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ⁸
870.1100	Acute Oral Toxicity: Rat	44942004	Merial Limited	PAY	
870.1200	Acute Dermal Toxicity: Rat	44942005	Merial Limited	PAY	
870.1300	Acute Inhalation Toxicity: Rat	48652806	Horizon Valley Generics, Inc.	OWN	Waive ¹⁰
870.2400	Primary Eye Irritation: Rabbit	44942006	Merial Limited	PAY	
870.2500	Primary Dermal Irritation	44942007	Merial Limited	PAY	
870.2600	Dermal Sensitization	44942008	Merial Limited	PAY	
870.7200	Companion Animal Safety	44942104	Merial Limited	PAY	
		45143901	Merial Limited	PAY	
		45612702	Merial Limited	PAY	
		47914237	Merial Limited	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

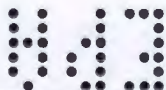
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Product Performance	44942105	Merial Limited	PAY	
		44942106	Merial Limited	PAY	
		45620501	Merial Limited	PAY	
		45620502	Merial Limited	PAY	
		45620503	Merial Limited	PAY	
		45620504	Merial Limited	PAY	
		45620505	Merial Limited	PAY	
		45620506	Merial Limited	PAY	
		45866902	Merial Limited	PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	48703501	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	See endnote ¹¹
		48703502	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
		48652701	Horizon Valley Generics, Inc.	PER	
		48703503	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013

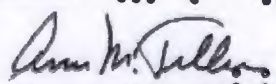


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DATA MATRIX

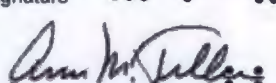
Date May 28, 2013		EPA Reg. No./File Symbol 88052-13		Page 5 of 8	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements - Fipronil					
850.2100 (71-1(a))	Acute Avian Oral Toxicity	42918617 42918618 43776601		OLD OLD OLD	See endnote ¹²
850.1075 (72-1)	Freshwater Fish Toxicity	42918624 42918673 42918674 42977902 43291718		OLD OLD OLD OLD OLD	See endnote ¹³
850.1010 (72-2(a)(b))	Freshwater Invertebrate Toxicity	42918625 44138301 42918669 42918671 43291719 46329902 46329903 46329905	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD OLD PAY PAY PAY	See endnote ¹⁴
Signature 		Name and Title Ann M. Tillman, Consultant		Date May 28, 2013	

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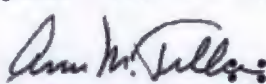
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200 (81-8)	Acute Neurotoxicity (Rat)	42918635 44262808 44431801		OLD OLD OLD	See endnote ¹⁵
870.3100 (82-1(a))	90-Day Oral Toxicity in Rodents	42918643 43501701 43559501 44963501	BASF Corporation	OLD OLD OLD PAY	See endnote ¹⁶
870.3150 (82-1(b))	90-Day Oral Toxicity in Non-Rodents	42918642 44262812		OLD OLD	
870.3200 (82-2)	21-Day Dermal Toxicity				Not required ¹⁷
870.3250 (82-3)	90-Day Dermal Toxicity			GAP	See endnote ¹⁸
870.3465 (82-4)	90-Day Inhalation Toxicity			GAP	See endnote
870.6100	28-Day Delayed Neurotoxicity - Hen				Not required ²⁰
870.6200	90-Day Subchronic Neurotoxicity - Rat	43291703		OLD	See endnote ²¹
870.4100 (83-1(a))	Chronic Toxicity Rat	42918648 43884003		OLD OLD	See endnote ²²
870.4200 (83-2(a))	Carcinogenicity Rat	42918648 43884003		OLD OLD	See endnote ²³
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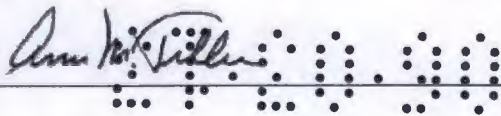
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4200 (83-2(b))	Carcinogenicity Mouse	42918649 43501702		OLD OLD	See endnote ²⁴
870.3700 (83-3)	Prenatal Development Toxicity Studies	42977903 42918646		OLD OLD	See endnote ²⁵
870.3800 (83-4)	Reproduction and Fertility Effects	42919647		OLD	See endnote ²⁶
870.6300 (83-6)	Developmental Neurotoxicity Study	44039002 44501102 44501103		OLD OLD OLD	See endnote ²⁷
870.5100 (84-2(a))	Bacterial Reverse Mutation Test	42918652		OLD	See endnote ²⁸
870.5300, 870.5375 (84-2(b))	<i>In vitro</i> Mammalian Cell Gene Mutation Test	42918651 42918653		OLD OLD	See endnote ²⁹
870.5385, 870.5395 (84-4)	<i>In vivo</i> Cytogenetics	43680801		OLD	See endnote
870.7200	Companion Animal Safety				See endnote ³⁰
870.7485	Metabolism and Pharmacokinetics	42918655 43253701		OLD OLD	See endnote ³²
870.7600 (85-2)	Dermal Penetration	43737308 44262816		OLD OLD	See endnote ³³
870.7800	Immunotoxicity			GAP	
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1100	Dermal Outdoor Exposure				Not required
875.1200	Dermal Indoor Exposure	44433302 44433303		OLD OLD	See endnote ³⁴
875.1300	Inhalation Outdoor Exposure				Not required
875.1400	Inhalation Indoor Exposure	44433302 44433303 44433308		OLD OLD OLD	
875.1500	Biological Monitoring				Not required
875.1600	Data Reporting and Calculations				Not required
875.1700	Product Use Information	Label		OWN	
835.2120 (161-1)	Hydrolysis	42977905		OLD	
Generic Data Requirements					
Horizon Valley Generic, Inc.'s C668.2 for Dogs qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements.					
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013



Endnotes for Data Matrix for C668.2 for Dogs

- ¹ **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** - This product does not consist solely of the technical grade active ingredient (TGAi) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** - These data are not required for registration of an end-use product.
- ⁴ **830.6316** - Neither the active ingredients, fipronil or S-methoprene, nor any of the inert ingredients in C668.2 for Dogs contains the chemical bonds or functional groups associated with chemicals that are explosive. EPA granted this waiver request.
- ⁵ **830.6317, 830.6320** - Storage stability and corrosion characteristic studies are in progress and will be submitted when the final report is completed.
- ⁶ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. C668.2 for Dogs is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- ⁷ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- ⁸ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** - These data are not required for registration of an end-use product.
- ⁹ **830.7520** - Horizon Valley Generics Inc. is seeking a waiver for this data requirement for C668.2 for Dogs because the product is not a fibrous material or a water-insoluble material. EPA granted this waiver request.
- ¹⁰ **870.1300** - A waiver from the requirement of an acute inhalation toxicity study is requested for this formulation. Based on the use pattern (a spot-on treatment for domestic animals), inhalation is not expected to be a significant route of exposure. EPA has previously waived this requirement for similar use products. A waiver request was provided in MRID 48652806 for a similar spot-on formulation, and EPA recommended this waiver be granted (EPA Review dated April 3, 2012, DP 398105). EPA granted this waiver request.
- ¹¹ Although these data were submitted by Channele Pharmaceuticals Manufacturing Ltd., Horizon Valley Generics Inc. has permission to cite these data from the sponsor of the studies, Klocke Verpackungs-Service GMBH.
- ¹² **850.2100** - These studies was cited in the EFED problem formulation as satisfying acute avian oral toxicity data requirements. Note: Although MB 46513 are cited here, HVG does not believe these data are required to support HVG's registration because MB 46513 is not an animal metabolite (see Scoping Document at 3).
- ¹³ **850.1075** - These studies was cited in the EFED problem formulation as satisfying freshwater fish toxicity data requirements. Note: Although MB 46513 are cited here, HVG does not believe these data are required to support HVG's registration because MB 46513 is not an animal metabolite (see Scoping Document at 3).
- ¹⁴ **850.1010** - These studies was cited in the EFED problem formulation as satisfying freshwater invertebrate toxicity data requirements. Note: Although MB 46513 are cited here, HVG does not believe these data are required to support HVG's registration because MB 46513 is not an animal metabolite (see Scoping Document at 3).
- ¹⁵ **870.3100** - This study was cited in the HED scoping document as satisfying acute neurotoxicity data requirements. In addition, this study was found acceptable in a Sept. 22, 1994 EPA review.

Endnotes for Data Matrix for C668.2 for Dogs

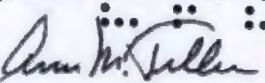
- ¹⁶ **870.3150** – This study was cited in the HED scoping document as satisfying 90-day oral toxicity in non-rodent data requirements. Note: Although MB 46513 are cited here, HVG does not believe these data are required to support HVG's registration because MB 46513 is not an animal metabolite (see Scoping Document at 3).
- ¹⁷ **870.3200** – Data are not required for nonfood uses.
- ¹⁸ **870.3250** – This guideline was identified as a data gap in the Data Call-In for the registration review of fipronil.
- ¹⁹ **870.3465** – This guideline was identified as a data gap in the Data Call-In for the registration review of fipronil.
- ²⁰ **870.6100** – Data are not required; no data have been submitted to satisfy this data requirement.
- ²¹ **870.6200** – This study was cited in the HED scoping document as satisfying subchronic neurotoxicity data requirements. In addition, this study was found acceptable in a Jan. 30, 1996 EPA review.
- ²² **870.4100** – This study was cited in the HED scoping document as satisfying chronic toxicity data requirements. In addition, this study was found acceptable in a May 12, 1994 EPA review.
- ²³ **870.4200** – This study was cited in the HED scoping document as satisfying carcinogenicity data requirements. In addition, this study was found acceptable in a May 12, 1994 EPA review.
- ²⁴ **870.4200** – These studies were cited in the HED scoping document as satisfying carcinogenicity data requirements. In addition, this study was found acceptable in a June 28, 1994 EPA review.
- ²⁵ **870.3700** – These studies were cited in the HED scoping document as satisfying prenatal development toxicity data requirements.
- ²⁶ **870.3800** – This study was cited in the HED scoping document as satisfying reproduction data requirements. In addition, this study was found acceptable in a May 12, 1994 EPA review.
- ²⁷ **870.6300** – These studies were cited in the HED scoping document as satisfying developmental neurotoxicity data requirement.
- ²⁸ **870.5100** – This study was cited in the HED scoping document as satisfying this data requirement.
- ²⁹ **870.5300, 870.5375** – These studies were cited in the HED scoping document as satisfying these data requirements.
- ³⁰ **870.5385, 870.5395** – This study was cited in the HED scoping document as satisfying this data requirement.
- ³¹ **870.7200** – Data are not required for the registration of a technical product; data will be cited, as appropriate with the end-use product.
- ³² **870.7485** – These studies were cited in the HED scoping document as satisfying metabolism data requirements.
- ³³ **870.7600** – This study was cited in the HED scoping document as satisfying dermal penetration data requirements.
- ³⁴ **875.1200** – HVG requests EPA use the data cited as a surrogate to satisfy this data requirement.

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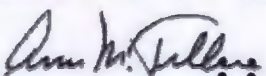
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not required ¹
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not Required ²
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not Required ³
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013

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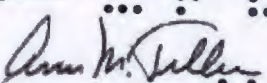
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Horizon Valley Generics, Inc.	OWN	Waiver ⁴
			Horizon Valley Generics, Inc.	OWN	PR-92-5 ⁵
					Not required ⁶
			Horizon Valley Generics, Inc.	OWN	PRN 92-53 ⁵
					Not required ⁷
			Horizon Valley Generics, Inc.	OWN	
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	
					Not Required [~]
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	Waiver ⁹
					Not Required ⁸
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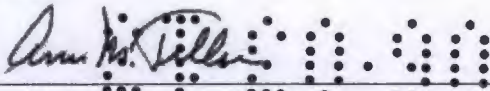
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					See 830.7560
					See 830.7560
					Not Required ⁸
					See 830.7840
					Not Required ⁸
			Merial Limited	PAY	
			Merial Limited	PAY	
			Horizon Valley Generics, Inc.	OWN	Waive ¹⁰
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
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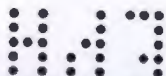
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			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Merial Limited	PAY	
			Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
			Horizon Valley Generics, Inc.	PER	
			Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013



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1201 Walnut Street, Suite 2900
Kansas City, MO 64106

Product

C668.2 for Dogs

Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)

Guideline Reference Number

Guideline Study Name

MRID Number

Submitter

Status

Note

OLD
OLD
OLD

See endnote¹²

OLD
OLD
OLD
OLD
OLD

See endnote¹³

BASF Corporation
BASF Corporation
BASF Corporation

OLD
OLD
OLD
OLD
OLD
PAY
PAY
PAY

See endnote¹⁴

Signature

Name and Title

Ann M. Tillman, Consultant

Date

May 28, 2013

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			BASF Corporation	OLD OLD OLD PAY	See endnote ¹⁶		
				OLD OLD			
					Not required ¹⁷		
				GAP	See endnote ¹⁸		
				GAP	See endnote ¹⁹		
					Not required ²⁰		
				OLD	See endnote ²¹		
				OLD OLD	See endnote ²²		
				OLD OLD	See endnote ²³		
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				OLD	See endnote ²⁴
				OLD	
				OLD	See endnote ²⁵
				OLD	
				OLD	See endnote ²⁶
				OLD	See endnote ²⁷
				OLD	
				OLD	See endnote ²⁸
				OLD	See endnote ²⁹
				OLD	
				OLD	See endnote ³⁰
					See endnote ³¹
				OLD	See endnote ³²
	OLD				
	OLD	See endnote ³³			
	OLD				
	GAP				
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 28, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date May 28, 2013			EPA Reg. No./File Symbol 88052-13		Page 8 of 8
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C668.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required
				OLD OLD	See endnote ³⁴
					Not required
				OLD OLD OLD	
					Not required
					Not required
				OWN	
				OLD	
			Signature 		





Horizon Valley Generics, Inc.

December 17, 2010

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

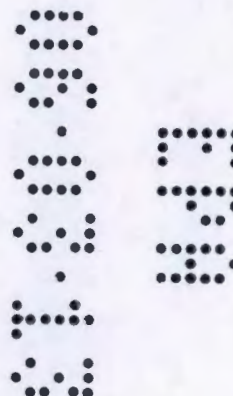
Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Horizon Valley Generics, Inc (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Bénédicte Deminière
CEO

cc: Pyxis Regulatory Consulting, Inc.



Horizon Valley Generics, Inc.

4561W 138th Ter

Leawood 66224 Kansas, USA

Contact at horizonvalleygenerics@horizonvalleygenerics.com

W

Fee for Service

{9362465~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 936246

EPA File Symbol/Reg. No.

88052-13

Pin-Punch Date:

6/3/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

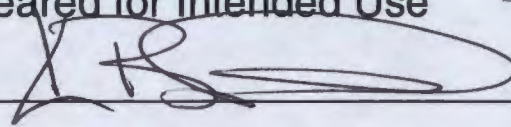
Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 6-4-13

Remarks:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 4, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC
HORIZON VALLEY GENERICS, INC.
4110 136TH ST. NW
GIG HARBOR, WA 98332-

PRODUCT NAME: C668.2 FOR DOGS
COMPANY NAME: HORIZON VALLEY GENERICS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 88052-13
EPA RECEIPT DATE: 06/03/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in cursive script, appearing to read "Liane Vrie", is written over the typed name.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: DMC Date 6/4/13 PM #: 10

EPA Reg. Number: <u>88052-13</u>		EPA Receipt Date: <u>6-3-13</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	✓		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?		✓	
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?		✓	
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?	✓		
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5	✓		
6	Is Label included? (5 copies)			
	a) Electronic Label submitted?			
Comments: <u>(MUP for Basic CSF) - NO more review needed</u>				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Horizon Valley Generics c/o Pyxis Regulatory Consulting Inc., 4110 138th St NW, Gig Harbor WA (253) 853-7389	EPA Registration Number/File Symbol 88052-13
Active ingredient(s) and/or representative test compound(s) Fipronil, S-Methoprene	Date 5/31/13
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor	Product Name C668.2 for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tillman</i>	Date 5/31/13	Typed or Printed Name and Title Ann M. Tillman, Agent
------------------------------------	-----------------	--

Material Sent for Data Extraction

Reg. # 88052-13

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 4-19-13

☐ Notification Dated _____

☒ New CSF(s) Dated 9-14-12

☐ Other: _____

☒ Decision #: 470216


☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 5-15-13

	ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001	EPA Registration No. 88052-13	Date of Issuance: April 19, 2013
	NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	Term of Issuance: Unconditional	
Name and Address of Registrant (include ZIP Code): Horizon Valley Generics, Inc. c/o Plyxis Regulatory Consulting, Inc. 4110 136 th Street NW Gig Harbor, WA 98332-9122			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p style="text-align: center;">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment: <ol style="list-style-type: none"> Revise the EPA Registration Number to read: "EPA Registration No 88052-13." This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient). You must submit the following data within the timeframe described below: Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability). 			
Signature of Approving Official: Refer to Page #3 Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch		Date: April 19, 2013	

5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2013. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Katlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot#
Where purchased: internet, store, Veterinarian
Active Ingredient(s)
Weight range for product
Date on which incident occurred, (mm/dd/yyyy)
State in which the incident occurred, (standard 2 letter abbreviation)
Registrant case #
Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds
Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:

- a. All minor dermal and ocular irritation reports.
- b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- d. Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- h. Table showing number of incidents for each dog breed.
- i. Table showing number of incidents in dog for each clinical sign.
- j. Table showing number of incidents in dog for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.

7. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

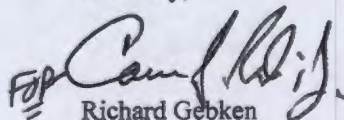
8. Horizon Valley Generics, Inc. must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site:
<http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Gebken", with a stylized flourish at the end.

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure:
088052-00013 10470216

Label Stamped "Accepted with Comments," dated April 19, 2013

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for**

3 x 0.023 FL. OZ. PACKAGE

3 x 0.045 FL. OZ. PACKAGE

3 x 0.091 FL. OZ. PACKAGE

3 x 0.136 FL. OZ. PACKAGE

(FRONT PANEL OF CARTON)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))

(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))

(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))

(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-RG

EPA Est. 74720-DEU-01

**ACCEPTED
With COMMENTS
In EPA Letter Dated:**

April 19, 2013

**Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

88052-13

C668.2 for Dogs - 4-18-2013- 88052-RG

1.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively kills and controls fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies 6-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

[EPA Reg. No. 88052-RG]

Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), [Deer ticks (*Ixodes scapularis*) which may carry Lyme disease]]
- [Rapidly controls infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the the same active ingredients fipronil and (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- Controls infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of sarcoptic mange mites]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Contains the same active ingredients as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

LABEL DIRECTIONS FOR PACKAGE INSERT

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 6 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

LABEL DIRECTIONS FOR PACKAGE INSERT

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea

have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

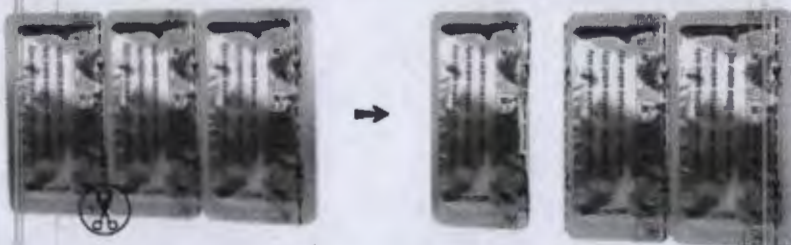
Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

LABEL DIRECTIONS FOR PACKAGE INSERT

To remove and open applicator:

- 1 Cut along scissor cut line to separate unit



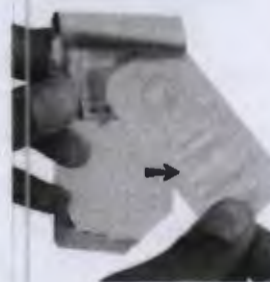
- 2 Turn unit over and cut corner at bulb end



- 3 From cut corner, peel backing completely off from bottom to top



- 4 Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

LABEL DIRECTIONS FOR PACKAGE INSERT

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-RG

[EPA Est. 74720-DEU-01]

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 6 to 132 lbs.

6-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

Text for CRP Blister and Pipette

TOP OF LIDDING FOIL—see back of blister on next page: Dotted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 6-22 lbs. and 8 weeks or older

0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

DO NOT USE ON CATS

0.023 fl. oz. - Use ONLY on Dogs & Puppies 6-22 lbs. and 8 weeks or older

0.045 fl. oz. - Use ONLY on Dogs & Puppies 23-44 lbs. and 8 weeks or older

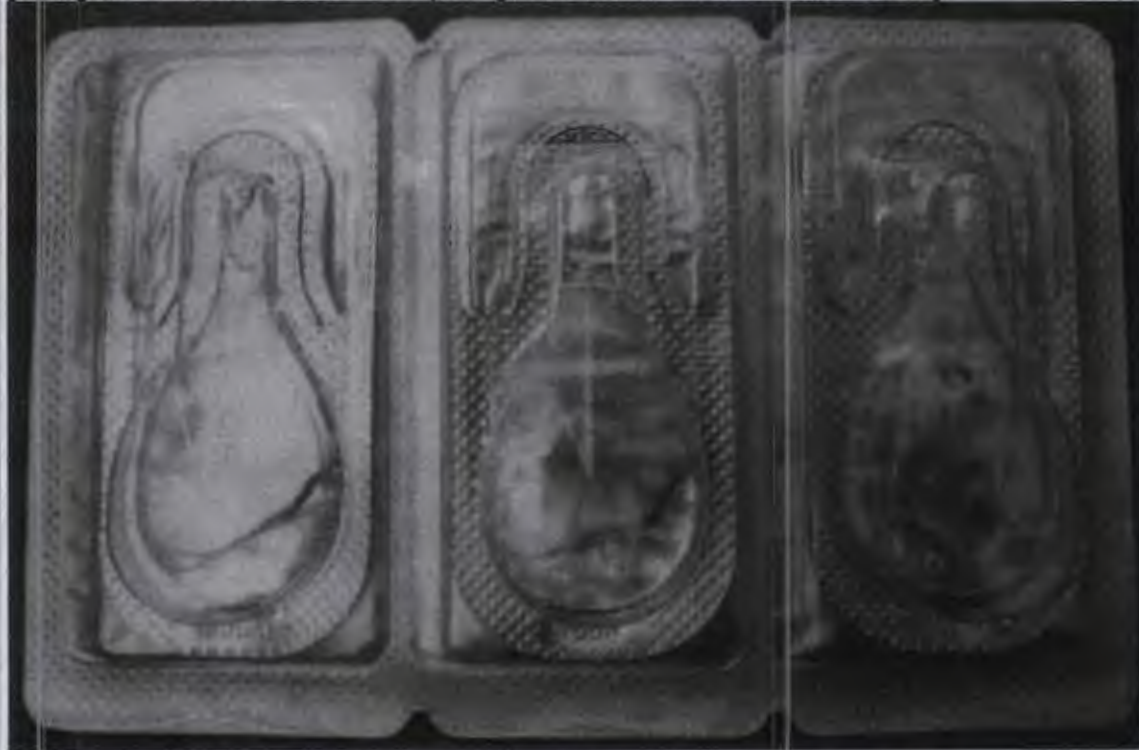
0.091 fl. oz. - Use ONLY on Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. - Use ONLY on Dogs & Puppies 89-132 lbs. and 8 weeks or older

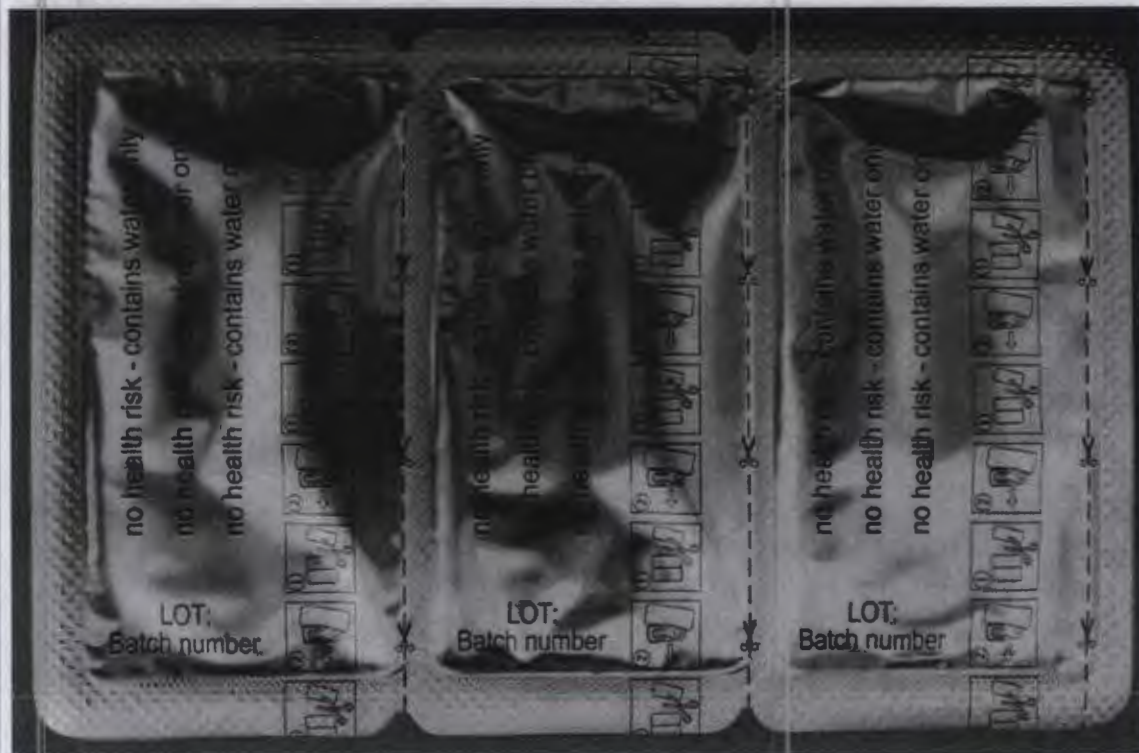
Fipronil 9.8%

(S)-Methoprene 8.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



Text for Reminder Stickers

[Optional marketing claims]

[Picture of Dog or Puppy 8 weeks or older]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Optional bar code]

Decision Seq: **470218** Action Code: **R310,NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS O ...**

FFS Start Date: **19-Oct-2012** Tentative Ind: **No** Start/Stop Clock: **FGPA Clock:**

Due Date: **19-Apr-2013** 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: **19-Oct-2012** FFS Original Decision: ...

Negotiated Due Date: 45-Day Due Date: **03-Dec-2012**

Registrant: **ic** Predecisional Due Date: **05-Apr-2013**

Response Due Date:

Current Status: **UNCONDITIONALLY REGISTERED (19-Apr-2013)**

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 934037	Rodia, Carmen	...	88052-13	19-Apr-2013 UNCONDITIONAL REGISTRATION W
Submission of further revised label.				
S: 928163	Rodia, Carmen	...	88052-13	19-Apr-2013 SUPERSEDED BY NEW RECEIPT
Revised label based on discussions with Roz.				
S: 924552	Rodia, Carmen	...	88052-13	19-Apr-2013 SUPERSEDED BY NEW RECEIPT
Initial application for a fipronil, s-methoprene product Spot on for dogs				

Rodia, Carmen

From: Gebken, Richard
Sent: Friday, April 19, 2013 9:22 AM
To: Rodia, Carmen
Subject: FW: Labels for 88052-RG (C668.2 for dogs.)
Attachments: 088052-RG.20130418.C668.2 for Dogs_changes tracked.pdf; 088052-RG.20130418.C668.2 for Dogs Label_clean copy.pdf

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Thursday, April 18, 2013 11:36 AM
To: Gebken, Richard
Subject: RE: Labels for 88052-RG (C668.2 for dogs.)

Richard,

The revised dog label is attached (changes tracked version is attached if that helps). I see that I didn't delete the [Alternate brand name] from the cat label so I will revise and resend to you.

Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

From: Gebken, Richard [<mailto:Gebken.Richard@epa.gov>]
Sent: Thursday, April 18, 2013 10:15 AM
To: Ann Tillman
Subject: RE: Labels for 88052-RG (C668.2 for dogs.)

Ann,

Attached is the label with my comments for the dog product.

Regards,

Richard

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Wednesday, April 17, 2013 2:58 PM
To: Gebken, Richard
Subject: Labels for 88052-RG (C668.2 for dogs.)

Richard,

I hadn't heard back from you regarding the questions I had from the reviews. I made most of the changes but am waiting for further direction from you on the Precautionary Statements and whether or not we can keep the one claim by adding the MRID to the data matrix.

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

From: Ann Tillman
Sent: Tuesday, April 16, 2013 10:43 AM
To: 'Gebken, Richard'
Subject: RE: Reviews for 88052-RG (C668.2 for dogs.)

Richard,

Originally, HVG used cite-all for companion animal studies. Back in November, Driss made us cite specific studies. According to Byron, we did not cite MRID 47914237 which would allow use on lactating and pregnant bitches. Is it too late to add this MRID to the data matrix to keep those animals on the label?

Attached
Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

From: Gebken, Richard [<mailto:Gebken.Richard@epa.gov>]
Sent: Monday, April 15, 2013 3:51 PM
To: Ann Tillman
Subject: Reviews for 88052-RG (C668.2 for dogs.)

Ann,

Attached are the reviews for 88052-RG. Please note that the CASS reviewer is recommending a minimum weight for the dogs and puppies based on the data cited. Please revise your label accordingly and return by COB tomorrow, so I can wrap both the cat and dog products up before April 19, 2013.

Regards,

Richard Gebken

S
To

From:

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for**

3 x 0.023 FL. OZ. PACKAGE

3 x 0.045 FL. OZ. PACKAGE

3 x 0.091 FL. OZ. PACKAGE

3 x 0.136 FL. OZ. PACKAGE

(FRONT PANEL OF CARTON)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing ~~56~~-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes

Kills all stages of Ticks, including those that may transmit Lyme disease

Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

~~{Alternate Brand Name}~~

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))

(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))

(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))

(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-RG

EPA Est. 74720-DEU-01

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target-kills and controls fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5-6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. ~~To eliminate mites, apply C668.2 for Dogs every 30 days.~~

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies ~~56~~-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

~~[Alternate brand name]~~

[EPA Reg. No. 88052-~~xxx~~RG]

Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea] larvae, [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), ~~and~~ [Deer ticks (*Ixodes scapularis*) ~~{~~which may carry Lyme disease}]
- [Rapidly ~~eliminates-controls~~ infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ~~the-vector~~ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the ~~[proven-effective]~~ ~~[topical]~~ the same active ingredients fipronil ~~plus-and~~ (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- ~~{~~EliminatesControls infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of ~~mites that cause sarcoptic mange~~ sarcoptic mange mites]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [~~Same formulation~~Contains the same active ingredients as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

LABEL DIRECTIONS FOR PACKAGE INSERT

C668.2 FOR DOGS

- (Use **ONLY** on dogs and puppies weighing ~~56~~-22 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

~~**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.~~

~~**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.~~

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. ~~Causes eye irritation. Avoid contact with skin, eyes or clothing.~~ Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. FOR USE ON DOGS AND PUPPIES ONLY. Do not use on puppies under ~~5-6~~ pounds or on puppies under 8 weeks of age. DO NOT USE ON CATS OR OTHER ANIMALS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

LABEL DIRECTIONS FOR PACKAGE INSERT

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Precaución al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

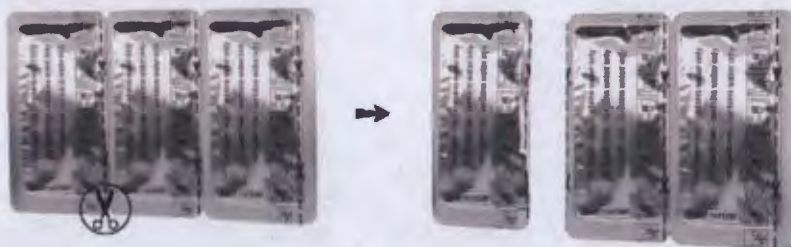
| Do not allow your dog to ingest this product. Do not apply to dogs weighing less than ~~5-6~~ pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

LABEL DIRECTIONS FOR PACKAGE INSERT

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. ~~To eliminate mites, apply C668.2 for Dogs every 30 days.~~

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

LABEL DIRECTIONS FOR PACKAGE INSERT

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-~~xxxx~~**RG**

[EPA Est. 74720-DEU-01]

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs ~~5-6~~ to 132 lbs.

56 -22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

Text for CRP Blister and Pipette

TOP OF LIDDING FOIL—see back of blister on next page: Dotted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-~~xxxx~~RG

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies ~~56~~-22 lbs. and 8 weeks or older

0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

DO NOT USE ON CATS

0.023 fl. oz. - Use ONLY on Dogs & Puppies ~~56~~-22 lbs. and 8 weeks or older

0.045 fl. oz. - Use ONLY on Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. - Use ONLY on Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. - Use ONLY on Dogs & Puppies 89-132 lbs. and 8 weeks or older

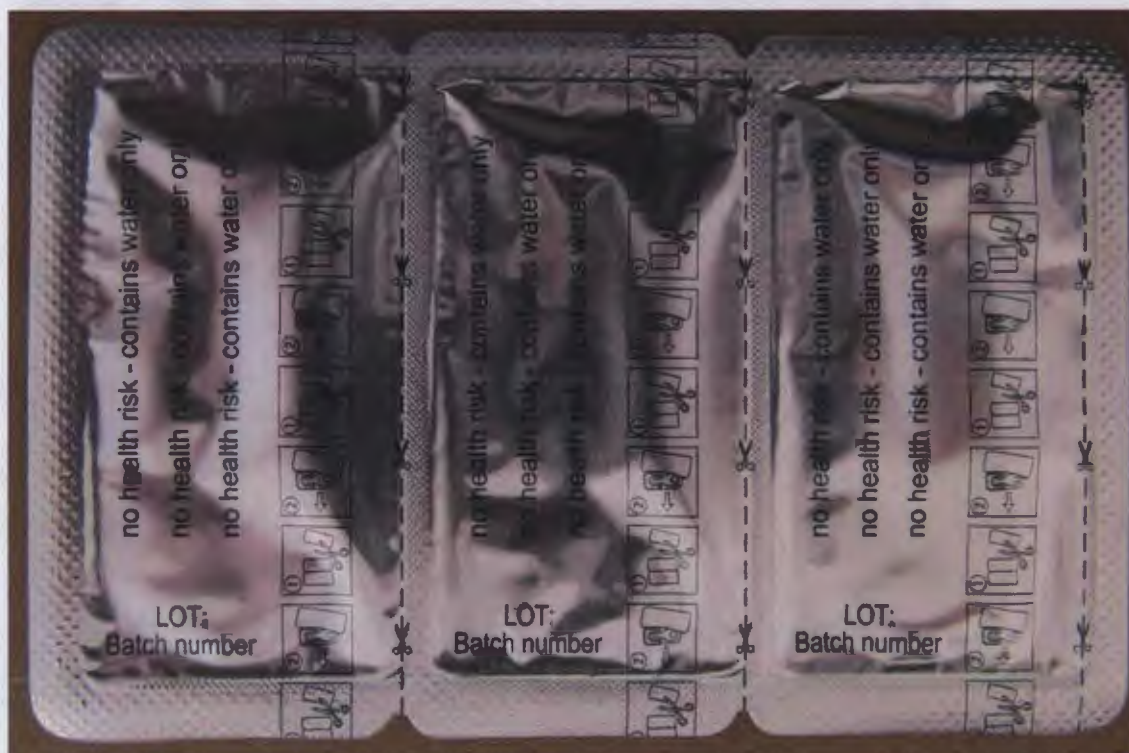
Fipronil 9.8%

(S)-Methoprene 8.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



Text for Reminder Stickers

[Optional marketing claims]

[Picture of Dog or Puppy 8 weeks or older]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

~~[Optional text with Company logo]~~

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

~~[Company name and logo]~~

[Optional bar code]

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for**

3 x 0.023 FL. OZ. PACKAGE

3 x 0.045 FL. OZ. PACKAGE

3 x 0.091 FL. OZ. PACKAGE

3 x 0.136 FL. OZ. PACKAGE

(FRONT PANEL OF CARTON)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))

(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))

(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))

(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-RG

EPA Est. 74720-DEU-01

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively kills and controls fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies 6-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

[EPA Reg. No. 88052-RG]

Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), [Deer ticks (*Ixodes scapularis*) which may carry Lyme disease]]
- [Rapidly controls infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the the same active ingredients fipronil and (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- Controls infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of sarcoptic mange mites]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Contains the same active ingredients as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

LABEL DIRECTIONS FOR PACKAGE INSERT

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENTS:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 6 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

LABEL DIRECTIONS FOR PACKAGE INSERT

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea

have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

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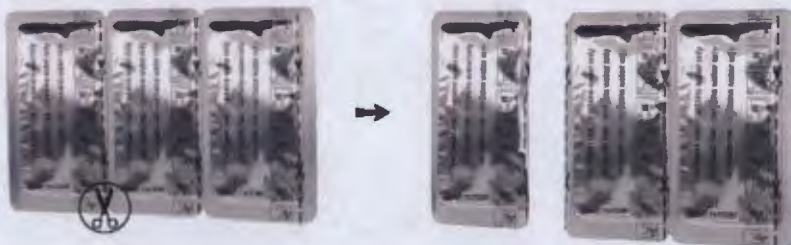
Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

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LABEL DIRECTIONS FOR PACKAGE INSERT

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

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Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

LABEL DIRECTIONS FOR PACKAGE INSERT

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-RG

[EPA Est. 74720-DEU-01]

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 6 to 132 lbs.

6-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

Text for CRP Blister and Pipette

TOP OF LIDDING FOIL—see back of blister on next page: Dotted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 6-22 lbs. and 8 weeks or older

0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

DO NOT USE ON CATS

0.023 fl. oz. - Use ONLY on Dogs & Puppies 6-22 lbs. and 8 weeks or older

0.045 fl. oz. - Use ONLY on Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. - Use ONLY on Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. - Use ONLY on Dogs & Puppies 89-132 lbs. and 8 weeks or older

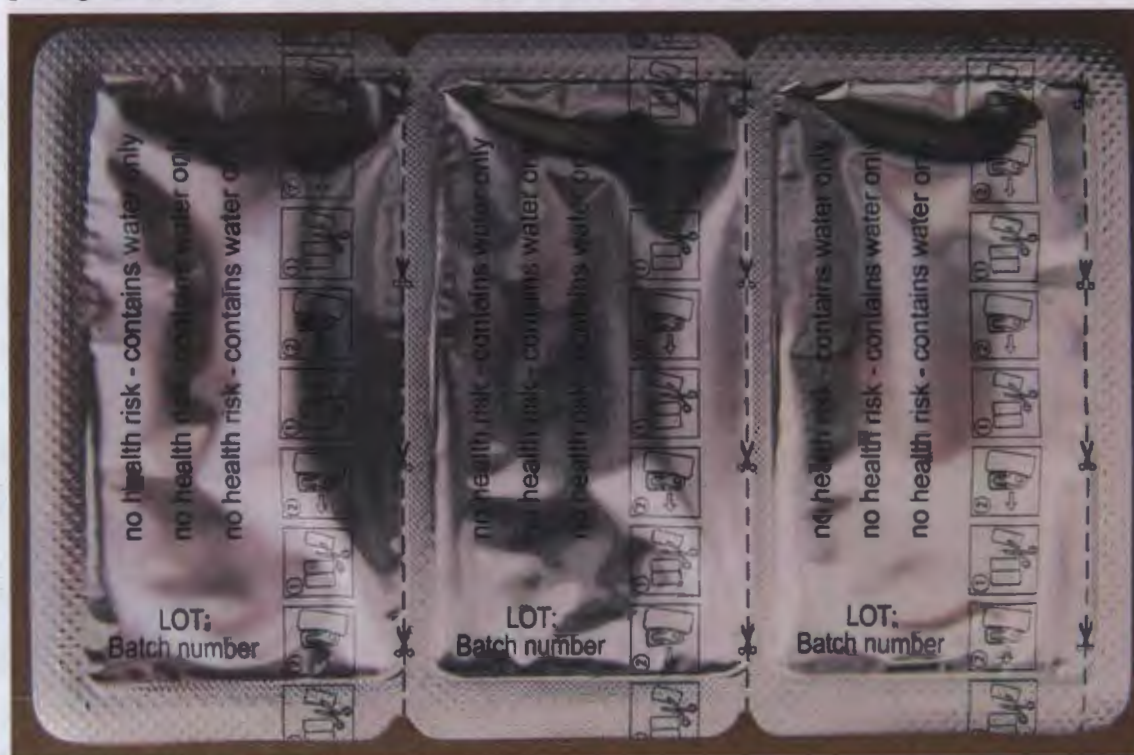
Fipronil 9.8%

(S)-Methoprene 8.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



Text for Reminder Stickers

[Optional marketing claims]

[Picture of Dog or Puppy 8 weeks or older]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Optional bar code]

Decision Information for 88052-RG

Decision Seq: 470216 Action Code: **310, NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS)** ...

FFS Start Date: 19-Oct-2012 Tentative Ind: No Start/Stop Clock: FGPA Clock:

Due Date: 19-Apr-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Dt: 21-Day Due Date: 19-Oct-2012 FFS Original Decision: ...

Negotiated Due Dt: 45-Day Due Date: 03-Dec-2012

Registrant: Response Due Date:

Current Status: PENDING (01-Oct-2012)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
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S: 928163	Benmhend, Driss	...	88052-RG	19-Apr-2013 PENDING
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Revised label based on discussions with Roz.

S: 924552	Benmhend, Driss	...	88052-RG	19-Apr-2013 PENDING
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Initial application for a fipronil, s-methoprene product Spot on for dogs

Viewing Record 1 of 1

CRP
CHEM
Prod E
Tox



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

Date: April 3, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode:406844

Decision no.: 470216

Submission no: 924552

Action code: R310

Product Name: C668.2 for Dogs

EPA Reg. No or File Symbol: 88052-RG

Formulation Type: RTU spot-on

Ingredients statement from the label with PC codes included: 9.8% fipronil (pc code: 129121) and 8.8% s- methoprene (pc code 105402)

Application rate(s) of product: prescribed volumes are applied. The amount applied to an animal is dependent upon animal weight.

Use pattern: dog spot-on product

OCSPP Guidelines: 810.3300

I. Action Requested: Review cited studies and new label.

II. Background: The registrant cited EPA Reg. No. 65331-5 (Frontline Plus for dogs, which contains the same levels of fipronil and s-methoprene as the subject product) as a substantially similar product.

III. Cited studies:

The registrant selectively cited the same efficacy data used to support EPA Reg. No. 65331-5. All study citations are for efficacy data on dogs. A copy of the cited label is attached.

Cited MRIDs
44942105
44942106
45620501

45620502
45620503
45620504
45620505
45620506
45866902

Fipronil dose calculations:

Fipronil is applied at the same rate as Frontline products –0.67 ml per 22 lbs of dog body weight. This application has been shown to be efficacious against ectoparasites of dogs listed on the label.

IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

1. The product label is acceptable provided the following change is made:

Sarcoptic mites. Remove "To eliminate mites, apply C668.2 for dogs every 30 days."

Decision Seq: 470216 Action Code: 2310, NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS) ...

FFS Start Date: 19-Oct-2012 Tentative Ind: No Start/Stop Clock FQPA Clock:

Due Date: 19-Apr-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 19-Oct-2012 FFS Original Decision: ...

Negotiated Due Date: 45-Day Due Date: 03-Dec-2012

Registrant: Response Due Date: Predecisional Due Date: 05-Apr-2013

Current Status: PENDING (01-Oct-2012)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
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S:928163	Rodla, Carmen	88052-RG	19-Apr-2013	PENDING
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Revised label based on discussions with Roz.

S:924552	Rodla, Carmen	88052-RG	19-Apr-2013	PENDING
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Initial application for a fipronil, s-methoprene product Spot on for dogs

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 406722
PC Code(s): 105402,129121
FOOD Use: No

EPA FILE SYMBOL NO.: 88052-RG DECISION NO.: 406722
ACTION CODE: R310

DATE OUT: March 05, 2013

SUBJECT: End Use Product Chemistry Review
Product Name: C668.2 for Dogs

FROM: Hari Mukhoty
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Driss Benmhend, CRM / Richard Gebkin PM - 10
Insecticide Branch / Registration Division (7505P)

Company Name: ~~Benide Products, Inc.~~ Horizon Valley Genetics, Inc
Formulation Type: Not provided.

INTRODUCTION:

The registrant has submitted one basic CSF (Dated: 09/14/2012), three alternate formulations (Alt. # 1, 2 & 3, CSFs dated: 09/14/2012) and has also proposed a product specific label for the registration of the aforesaid products under EPA File Symbol No. 88052-RG. The registrant submitted product chemistry Group A and Group B data under MRID(s): 489558-01, -02, -03 and -04.

TRB has been requested to evaluate the product chemistry data required for registration of the proposed products.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.8%), (S) Methoprene (8.8%).
2. Has the registrant claimed substantial similarity to registered product?
[X] Yes [X] No [] NA If yes: EPA Reg. No. 65331-5
3. The source material(s) of the active ingredient(s) is/are registered with the Agency.
4. All inert ingredients have been approved by IIAB on 10/02/2012 for Non-food uses (Only on Dogs & Puppies to kill Fleas, Lice, Mosquitoes, Ticks that may spread Lyme disease & aids to control sarcoptic mange mite infestations).
5. The CSFs of the proposed basic formulation and alternate formulations have been filled out completely and correctly.

DP BAR CODE NO.: 406722
PC Code(s): 105402,129121
FOOD Use: No

EPA FILE SYMBOL NO.: 88052-RG DECISION NO.: 406722
ACTION CODE: R310

6. Confidential Statement of Formula(s):

☒ Basic - Dated: 09/14/2012 re-submitted - Dated: NA
☐ Alternate #1, 2 & 3 Dated: " re-submitted: Dated: NA

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐. Alternate CSF is not acceptable for other changes needed to become acceptable.

7. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)
☒ Yes

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"
, if not, explain below:

Metallic equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA;
Soluble arsenic:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Isomeric ratios:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Acid equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown? Flash point > 300° F

☐ Yes ☒ No The label contains a Physical or chemical hazard statement for containers for mixing, storing and applying for the product.

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☐ No ☒ NA

d. Label requires an additional Storage and Disposal statement: ☒ Yes ☐ No

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 406722
 PC Code(s): 105402,129121
 FOOD Use: No

EPA FILE SYMBOL NO.: 88052-RG DECISION NO.: 406722
 ACTION CODE: R310

8. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 489558-01, -02
			Yes	No		
830.1550	Product Identity & Composition		X		A	"
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			X	NA	As stated in CSFs dated: 09/14/2012
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	
		Justification for wider limits				
830.1800	Enforcement analytical method #		X		A	

A = Acceptance, N = Not Acceptable, G = Data Gap,

W = Waiver Request, I = In Progress, NA = Not Applicable

Analytical Method: HPLC using UV-VIS detector set at 215 (Fipronil) / 270 (S- Methoprene) nm.

Validation was performed for accuracy, precision and linearity.

DP BAR CODE NO.: 406722
PC Code(s): 105402,129121
FOOD Use: No

EPA FILE SYMBOL NO.: 88052-RG DECISION NO.: 406722
ACTION CODE: R310

9. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 489558-03 & -04 Self-Certified
830.6303	Physical State	Liquid	A	"
830.6315	Flammability	Not Flammable	A	"
830.6316	Explodability	Not potentially explosive	A	"
830.7000	pH	5.79	A	"
830.7300	Density	1.032 g/mL	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress.

CONCLUSIONS:

1. TRB has reviewed the CSFs (dated: 09/14/2012) for the proposed basic and alternate formulations and has found them to be acceptable. The CSFs are attached with this review and could be located in OPPIN CHEM DOCS.

2. The proposed product is considered substantially similar to the cited product (65331-5; Frontline Plus for Dogs). Label text indicates both aforesaid products are to be used on Dogs only.

3. Product chemistry Group A data are satisfied and acceptable. Group B data, with the exception of Storage Stability (830.6317) and Corrosion Characteristics (830.6320) are acceptable.

4. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.

5. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

February 22, 2013

MEMORANDUM:

Subject: Name of Pesticide Product: C668.2 FOR DOGS
EPA Reg. No. /File Symbol: 88052-RG
DP Barcode: DP 406842
Decision No.: 470216
Action Code: R310
PC Codes: 105402 (S-Methoprene: 8.8%)
129121 (Fipronil: 9.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Feb-22-2013
M. Hashim
Toxicologist / T.R.

To: Driss Benmhend/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: HORIZON VALLEY GENERICS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.8%
105402 (S)-Methoprene	8.8%
<u>Other Ingredient(s):</u>	<u>81.4%</u>
TOTAL	100.0%

ACTION REQUESTED: "...I am attaching the Toxicity and Companion Animal Safety data submitted by Horizon Valley Generics to support the application to register the new end-use product C668.2 for Dogs containing the active ingredients Fipronil and methoprene..."

BACKGROUND: The material received for review includes a cover letter (dated September 27, 2012), two data matrices (one is dated September 27, 2012; the second is dated November 14, 2012), a proposed label (signal word CAUTION) and one basic and three alternate CSFs (all dated September 14, 2012). According to the label, the proposed dosages (for dogs and puppies 8 weeks or older) are 0.67 mL (0.023 fl. oz.) for the weight range of 5-22 lbs; 1.34 mL (0.045 fl. oz.) for 23-44

lbs; 2.68 mL (0.091 fl. oz.) for 45-88 lbs; and 4.02 mL (0.136 fl. oz.) for 89-132 lbs. The label includes the statement: "Do not reapply C668.2 for Dogs for 30 days."

COMMENTS AND RECOMMENDATIONS:

1. According to the data matrix dated September 27, 2012 the registrant is using cite-all to address the acute toxicity and companion animal safety data requirements. In the data matrix dated November 14, 2012 the registrant is citing specific MRIDs (most originally submitted by Merial Limited) to satisfy the acute toxicity and companion animal safety data requirements. TRB considers the data matrix dated November 14, 2012 as superseding that of September 27, 2012, and this review is based on that consideration.
2. To satisfy all acute toxicity data requirements except the inhalation study, the registrant has cited 5 acute toxicity studies (MRIDs 44942004 through 44942008). According to our records, these studies have been previously reviewed by TRB (memorandum dated December 12, 1999 for 65331-U, now 65331-4) and classified as acceptable.
3. After comparing the CSFs of 88052-RG and 65331-4, TRB concludes that acute toxicity and companion animal safety studies that were used to support 65331-4 will also support 88052-R. Therefore MRIDs 44942004 through 44942008 will satisfy all acute toxicity data requirements for 88052-R except for the inhalation study.
4. For the inhalation study requirement, the registrant has submitted a data waiver request that was originally reviewed (as MRID 48652806) for 88052-G (now 88052-3). From TXR 5013686 (dated April 3, 2012): From p. 6 of MRID 48652806: "Inhalation is not expected to be a significant route of exposure because the actual containers are child-resistant packages that contain an applicator which is fully enclosed in a foil backed blister package. Each applicator holds less than 0.2 fluid ounces of formulation (actual contents are 0.017, 0.023, 0.045, 0.091 and 0.136 *[the amounts proposed for 88052-RG are 0.023, 0.045, 0.091 and 0.136 fluid ounces]*..."

In the review of April 3, 2012 it was stated that TRB recommends for this waiver, based on the use pattern (a spot-on treatment for domestic animals) and it was noted that EPA has previously waived this requirement for similar-use products. Based on the oral and dermal acute toxicity of this formulation and the low exposure potential it was stated that 88052-3 could be assigned to EPA Toxicity Category IV by the inhalation exposure route. The same argument is applicable to 88052-RG, and an inhalation study waiver (with assignment to category IV by that exposure route) is appropriate.

5. The following is the acute toxicity profile of 88052-RG, based on the considerations given above:

Acute oral toxicity	III	Cited	MRID 44942004
Acute dermal toxicity	IV	Cited	MRID 44942005
Acute inhalation toxicity	IV	Waived	[MRID 48652806]
Primary Eye irritation	IV	Cited	MRID 44942006
Primary Dermal Irritation	IV	Cited	MRID 44942007
Dermal Sensitization	Negative	Cited	MRID 44942008

6. Based on the acute toxicity profile as well as information from the Confidential Statement of Formula and the uses indicated on the proposed label, the following is the precautionary and first aid labeling for 88052-RG as obtained from the TRB Label Review System:

PRODUCT ID #: 088052-00013

PRODUCT NAME: C668.2 FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

7. The registrant has cited MRIDs 44942104, 45143901 and 45612702 to satisfy the companion animal data requirement(s). The study in MRID 44942104 is an interim report in which the test material (containing fipronil: 10% w/v and (S)-methoprene: 9% w/v) was topically applied at dose levels of 0.133 (1X), 0.399 (3X) and 0.665 (5X) mL/kg to groups of 6 male and 6 female beagle puppies (52-60 days old at initiation) on test day 1 and again on test day 29. A group of controls received no treatment. This study was originally classified as supplementary (TXR 5001488, TRB memorandum dated May 5, 2000). Subsequently, additional material (MRID 45143901) was received, and the complete study (in MRIDs 44942104 and 45143901) was classified as acceptable (TXR 5001489, dated July 11, 2000). In TXR 5001489 it was stated: "This reviewer's conclusion is that the 1X dosage rate in the study would support an application rate of 0.67 mL for puppies and dogs weighing ≥ 5 kg ($0.67 \text{ mL/kg} \div 5 = 0.133 \text{ mL/kg}$), **but not for dogs weighing less than 5 kg (=11 lbs)**. If the registrant wishes to propose the use of this product on smaller dogs (those weighing less than 5 kg) then the doses must be adjusted accordingly (for example, we could accept a dosage rate of 0.333 mL for dogs weighing between 5.5 and 11 lbs)."

8. In response to the TRB review of July 11, 2000 an additional companion animal (8 week old puppies) safety study (MRID 45612702) was submitted. From the executive summary of the TRB review (TXR 5005723) of this study:

"In a companion animal safety study (MRID 456127-02), Frontline Plus (active ingredients: 10% w/v fipronil and 9% w/v {S}-methoprene) was topically applied (between the base of the skull and the shoulder blades at one or more spots) to eight week old dogs weighing less than 11 lbs at 1x, 3x and 5x the prepackaged use (0.67 mL/ puppy) dosage. Forty-eight beagle dogs (24/sex) were randomly allocated to one control and 3 treatment groups with 6 male and 6 female animals in each group. Controls received no treatment. The formulation was delivered from the marketed (0.67 mL) pipettes having 67 mg of fipronil and 60.3 mg of S-methoprene as 1x dosage. Puppies were exposed to the formulation only on Day 1, when they were at an average age of 57 (50 to 63) days and weighed 1.67 to 3.57 kg...

"There were no deaths on the study, no local reaction on the application site and no treatment-related clinical signs in the measured parameters. There were no effects on rectal temperature, body weight, food and/or milk consumption, hematology or clinical chemistry.

"Gross necropsy and histopathology revealed no abnormalities, with possible exception of a few dermal effects at the treated sites (red area on the treated site in a few dogs which in one 3x male was 30 mm in diameter, and in another one 3x male was 10 mm in diameter, pages 84, 174, 176).

"A single topical application of fipronil (10% w/v) and (S)-methoprene (9% w/v) in a solution at 1x, 3x and 5 times the maximum recommended dose, when given to eight week old dogs (approx. 1.5-3.5 kg) showed no treatment related effects.

"This study (870-7200) is classified **Acceptable** in demonstrating a 5x margin of safety in dogs 8 weeks old or older and weighing less than 11 lbs."

9. Group mean bodyweights (by sex) are reported on p. 35 of MRID 45612702, and the individual bodyweights are reported on pp. 113-114. From p. 35 the mean weight \pm S.D. for Group 4 males on Day 1 was 2.44 ± 0.61 kg ($=5.38 \pm 1.34$ lbs), and for Group 4 females on Day 1 was 2.69 ± 0.50 kg (5.93 ± 1.10 lbs). From p. 113 the Day 1 range of body weights for Group 4 males was 1.80 to 3.57 kg ($=3.97$ to 7.87 lbs) and (from p. 114) for Group 4 females was 2.27 to 3.45 kg ($=5.00$ to 7.61 lbs). The mean body weight \pm S.D. on Day 1 for all 12 puppies was 2.56 ± 1.20 kg ($=5.64 \pm 2.65$ lbs).

Based on the day 1 mean body weights of the 5X puppies and the absence of toxicity in this group in the study in MRID 45612702, we can accept a 6 lb minimum puppy (or dog) body weight.

The companion animal safety data citations (MRIDs 44942104, 45143901 and 45612702) then support a minimum 8-week age and a minimum 6 lb puppy (or dog) body weight (rather than the 5 lbs indicated on the proposed label for 88052-RG).

10. The proposed label includes the statement: "C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches." This claim is not supported by the cited studies and must be deleted.
11. At the top of page 1 of the proposed label the "6 x 0.23 FL. OZ." and "6 x 0.45 FL. OZ." should be revised to "6 X 0.023 FL. OZ." and "6 x 0.045 Fl. OZ." respectively.
12. The TRB chemistry team should review and accept the basic and alternate CSFs dated September 14, 2012.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 11/14/2012 OUT 12/3/2012

RD, TRB, Reviewed by Rosalind L. Gross 12/3/2012

EPA Reg. No. or File Symbol 88052-RG

DP Barcode DP406751

Decision # 470216

EPA Petition or EUP No. _____

Date Division Received 9/27/12

Type Product(s) Insecticide (flea product)

Data Accession No(s). _____

Product Mgr./Chemical Review Mgr./Contact Person RM 10 Driss Benmhend

Division RD

Product Name(s) C668.2 for Dogs

Company Name(s) Horizon Valley Generics, Inc.

Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for this product

Active Ingredient(s), PC code, & %
Fipronil 9.8%
S-Methoprene 8.8%

Summary of Findings

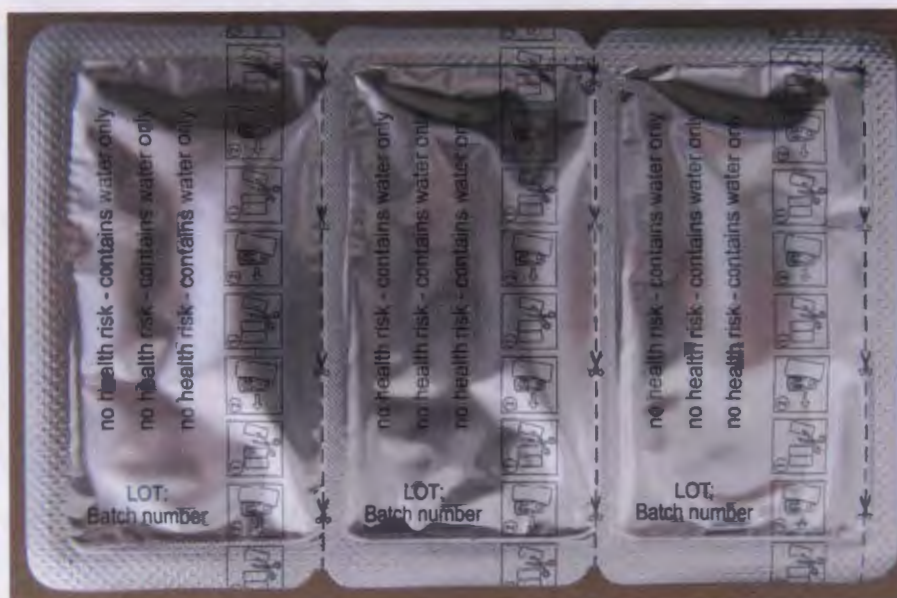
In conclusion all the requirements for CRP have been met for EPA Registration No. 88052-RG. The directions on opening the package given to consumers must be identical to those given to the seniors during testing (see packaging section below). For details see Analysis of Data and Conclusions section below.

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package is a pipette in a blister. The pipette has clear plastic front and foil backing. The blister is the Child-Resistant Packaging, CRP. The blister backing is PET/AL/PET/PE 12/12/12/75, which appears as a foil color. The blister front is PET/PP/PE transp. LDPE 350/100/75, which appears as a clear color. Three blisters are attached to each other to form one card. There are 4 fill volumes 0.67ml, 1.34ml, 2.68ml, and 4.02ml.

The Senior Adult Use Effectiveness Testing, SAUE, directions on the back of the blister are a pictorial showing the separation of one of the three attached blisters and removing the pipette from the blister that repeats for the height of the blister and a dashed line with a picture of a scissors to the right of the pictorial showing where to separate one of the three attached blisters (see picture below). In addition to the SAUE directions on the back of the blister, there are also SAUE directions in a leaflet that were given to the test subjects. There is a set of instructions used for all 4 fill volumes, which is referred to in this review as Package Instructions for SAUE Testing Set 2 (see picture below for set of SAUE Testing directions). EPA Registration No. 88052-RG is for fill volumes 0.67ml, 1.34ml, 2.68ml, 4.02ml.



Back of Blister with Opening Instructions

Opening Instructions from Package Leaflet

OPENING INSTRUCTIONS FOR USE

- 1** Cut along scissor cut line to separate unit
- 2** Turn unit over and cut corner at bulb end
- 3** From cut corner, peel backing completely off from bottom to top
- 4** Remove the applicator

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 www.klocke.com

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Package Instructions for SAUE Testing Set 2

Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals **28.5mg**. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x 0.098 Fipronil] = **0.28ml** for EPA REG No. 88052-RG.

A child failure is access to one blister of any size equal to or greater than 0.28ml for EPA REG No. 88052-RG.

Failure

For the purposes of CRP testing EPA REG No. 88052-RG **a child failure is access to one blister** for all sizes. Access to one blister is more than a toxic or harmful amount of Fipronil (28.5mg) for all sizes.

Child Failure is defined as access to one blister, any breach, rip, tear, hole, or penetration of the blister, any visible incision or opening of the blister, any leakage of placebo from blister during or after test, or any partial or complete access to the placebo (water).

Senior Failure is failure to access the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or inability to remove the pipette in the blister in condition suitable for intended use or removal of the pipette in the blister resulting in significant exposure to pipette contents.

Analysis of Data and Conclusion

The CRP certification for EPA REG No. 88052-RG dated September 27, 2012 is acceptable. The label for EPA REG No. 88502-RG (0.67ml, 1.34ml, 2.68ml, 4.02ml) submitted November 14, 2012 uses the same SAUE directions that are on the back of the blister and the Package Instructions for SAUE Testing **Set 2** that were given to the seniors during CRP testing (see packaging section for exact instructions).

Provided EPA REG No. **88052-RG** is being packaged into the CRP blister in strips of three blisters per card by Klocke Verpackungs-Service GMBH in Germany the data matrix citations for MRID 48703501, 48703502, 48703503, and 48652701 for EPA REG No. **88052-RG** demonstrate the CRE requirements in 16 CFR 1700.20 and SAUE effectiveness specifications in 16 CFR 1700.15(b)(2)(i) when tested in accordance with 16 CFR 1700.20 are met.

For the results for the 0.67, 1.34, and 4.02ml sizes see MRID 48703501, 48703502, and 48703503 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R]. The results for 2.68ml size see MRID 48652701 in review by Rosalind L. Gross April 19, 2012

[DP398108, 399748, 398115, 399746, 398123, 399747, 398262, 399749, 399560, 399565; EPA Registration No. 88052-G, 88052-R, 88052-E, 88052-L, 88052-A, 88052-T].

In conclusion all the requirements for CRP have been met for EPA Registration No. 88052-RG. The directions on opening the package given to consumers must be identical to those given to the seniors during testing (see packaging section).

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

Novmeber 15, 2012

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Horizon Valley Generics, Inc.
C668.2 for Dogs (EPA File Symbol 88052-RG)
OPP Decision Number D-470216
Submission of Revised Label

Dear Mr. Gebken,

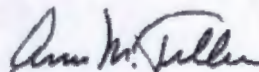
On behalf of Horizon Valley Generics, Inc., I am submitting a revised label for C668.2 for Dogs based on discussions with Rosalind Gross. Please forward a copy of this revised label to Driss Benmhend and Rosalind Gross. This label replaces the version sent with the application for registration on September 27, 2012.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Three (3) Copies of the Proposed Labeling for C668.2 for Dogs
3. A CD containing an electronic version of the label
4. Certification with Respect to Label Integrity
5. Letter of Authorization

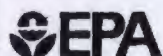
We trust you will find this submission complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Horizon Valley Generics Inc./88052-RG	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Horizon Valley Generics Inc./C668.2 for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Horizon Valley Generics Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-5 Product Name Frontline Plus for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised label per discussion with EPA reviewer.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136	No. per container 3
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other on box and on insert inside box	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 11/15/12	

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

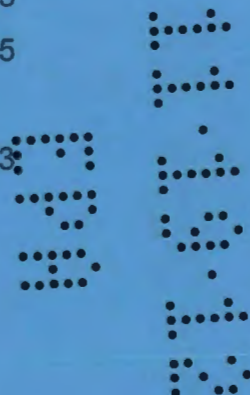
then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

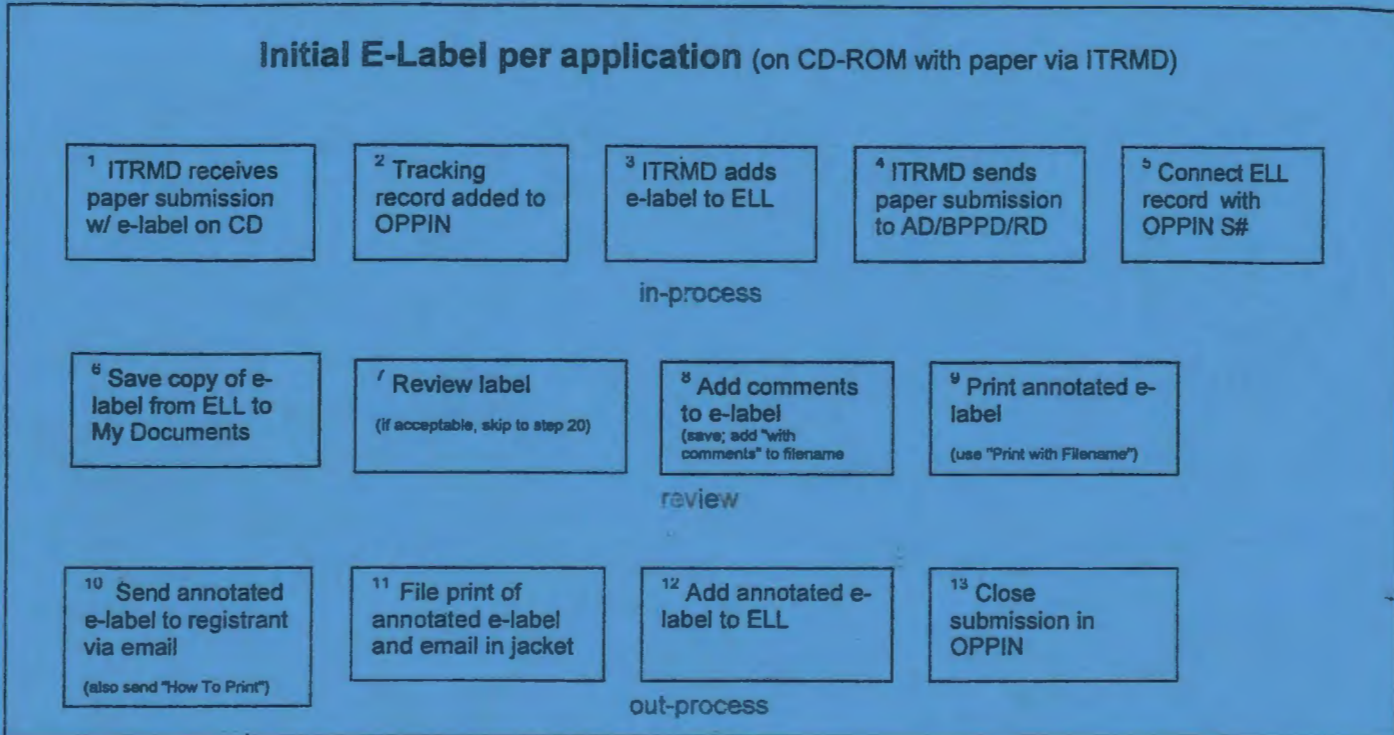


PROCESSING ELECTRONIC LABELS

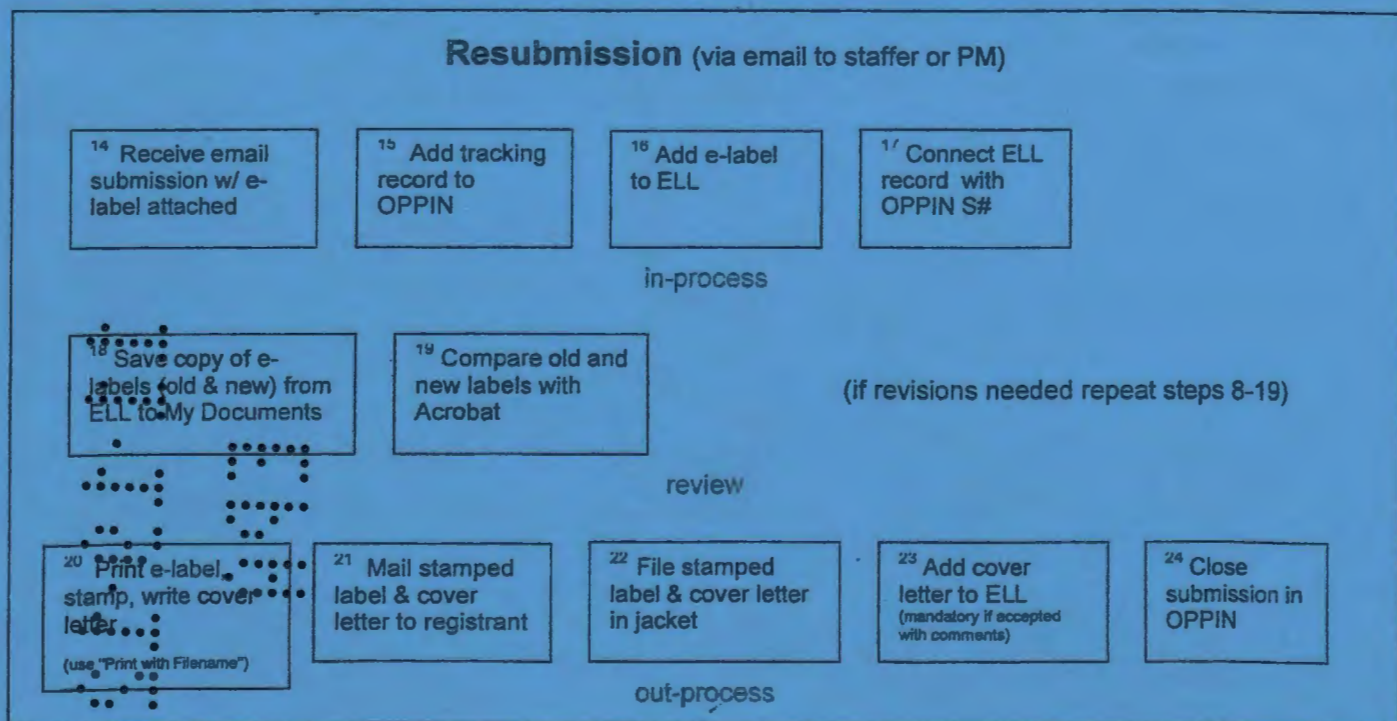
(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)



Resubmission (via email to staffer or PM)



process - big picture

- 1- create OPPIN tracking
- 2- put label in ELL; link to S#
- 3- save ELL label to MyDocuments
- 4- compare / comment
- 5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

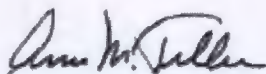
Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

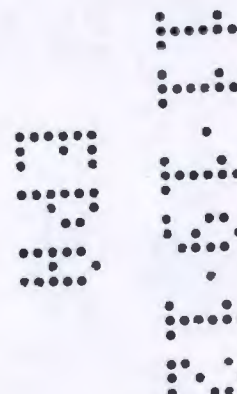
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088052-RG	Nov. 15, 2012	088052-RG.20121114.C668.2 for Dogs label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent for Horizon Valley Generics, Inc.

Nov. 15, 2012
Date





Horizon Valley Generics, Inc.

December 17, 2010

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

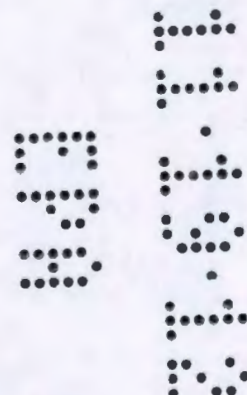
Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Horizon Valley Generics, Inc (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Bénédicte Deminière
CEO

cc: Pyxis Regulatory Consulting, Inc.



OK CRP 11-19-12

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for**

- 3 x 0.023 FL. OZ. PACKAGE**
- 3 x 0.045 FL. OZ. PACKAGE**
- 3 x 0.091 FL. OZ. PACKAGE**
- 3 x 0.136 FL. OZ. PACKAGE**

(FRONT PANEL OF CARTON)

C668.2 FOR DOGS

- (Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older; picture of dog in weight class)
- (Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)
- (Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)
- (Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]
[Alternate Brand Name]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENT:

Fipronil	9.8%
(S)-Methoprene.....	8.8
OTHER INGREDIENTS:	<u>81.4%</u>
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for **FIRST AID** and **PRECAUTIONARY STATEMENTS**

NET CONTENTS:

- (0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))
- (0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))
- (0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))
- (0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-RG

EPA Est. 74720-DEU-01

C668.2 for Dogs - 11-14-2012 - 88052-RG

1.

Manufactured for:
Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany
C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.



To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies 5-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

[Alternate brand name]

[EPA Reg. No. 88052-xxx]

Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), and Deer ticks (*Ixodes scapularis*) [which may carry Lyme disease]]
- [Rapidly eliminates infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills the vectors that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the [proven effective] [topical] fipronil plus (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of mites that cause sarcoptic mange]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Same formulation as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

LABEL DIRECTIONS FOR PACKAGE INSERT

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENT:

Fipronil	9.8%
(S)-Methoprene.....	8.8
OTHER INGREDIENTS:	81.4%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 5 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

LABEL DIRECTIONS FOR PACKAGE INSERT

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

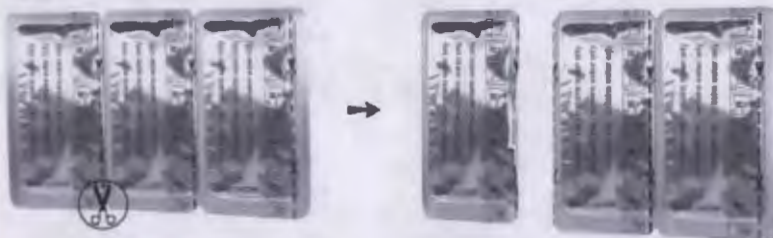
Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

LABEL DIRECTIONS FOR PACKAGE INSERT

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



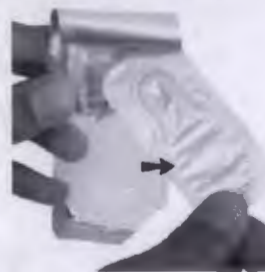
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

LABEL DIRECTIONS FOR PACKAGE INSERT

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-xxxx

[EPA Est. 74720-DEU-01]

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 5 to 132 lbs.

5-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

Text for CRP Blister and Pipette



TOP OF LIDDING FOIL—see back of blister on next page: Dotted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-xxxx

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 5-22 lbs. and 8 weeks or older

0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C668.2 for Dogs

EPA Reg. No. 88052-RG

Lot/Batch No.

DO NOT USE ON CATS

0.023 fl. oz. - Use ONLY on Dogs & Puppies 5-22 lbs. and 8 weeks or older

0.045 fl. oz. - Use ONLY on Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. - Use ONLY on Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. - Use ONLY on Dogs & Puppies 89-132 lbs. and 8 weeks or older

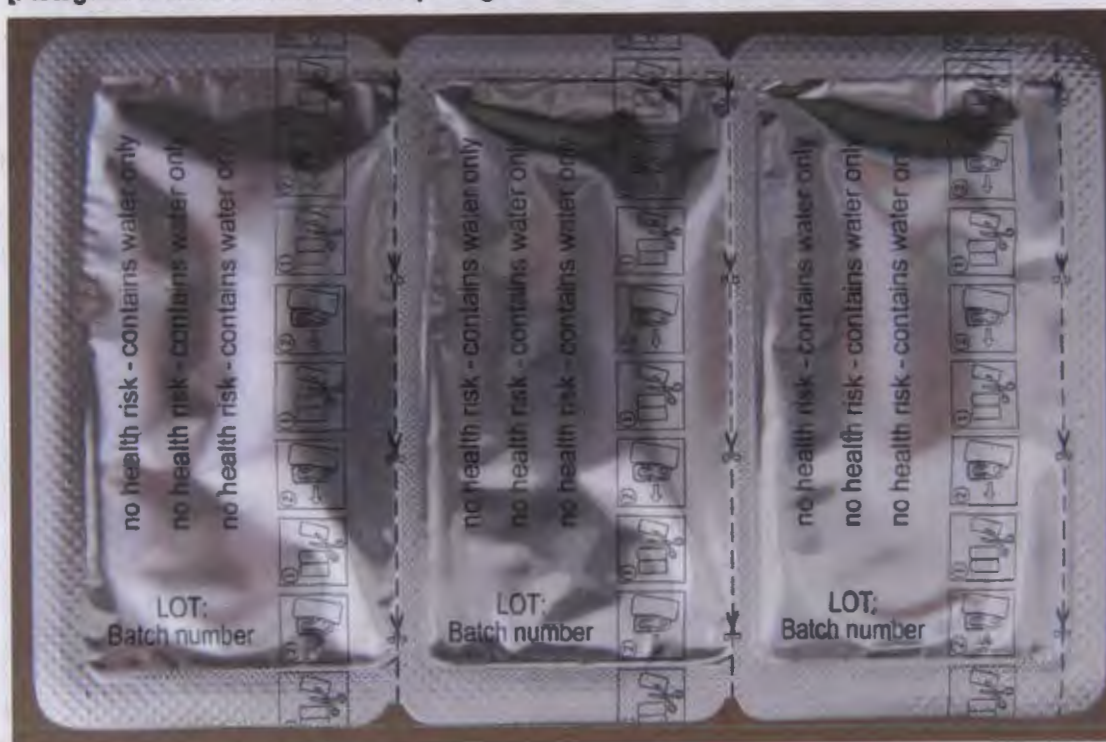
Fipronil 9.8%

(S)-Methoprene 8.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



Text for Reminder Stickers

[Optional marketing claims]

[Picture of Dog or Puppy]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

[Optional text with Company logo]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Company name and logo]

[Optional bar code]

Revised Label for C668.2 for Dogs and C710.0 for Cats, File Symbols 88052-RG and 88052-RU (D-470216, D-470254)

Ann Tillman to: Driss Benmhend

11/16/2012 10:36 AM

Cc: Rosalind Gross

History: This message has been replied to.

Driss,

I spoke with Rosalind Gross about the labels for Horizon Valley Generic's applications for registration of C668.2 for Dogs and C710.0 for Cats and I agreed to make changes to the labels revising the package size. I redated the label, inserted the file symbols, and clarified which text is found on the pipette foil vs. the CRP foil.

The revised labels for these two products are attached. Please replace the versions that were sent with the applications submitted for registration back on September 27, 2012. Yesterday, I sent out these replacement labels and administrative documents via courier delivery to Richard Gebken.

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com



088052-RG.20121114.C668.2 for Dogs Label.pdf 088052-RU.20121114.C710.0 for Cats Label.pdf

Replace with 11-14-12 label

(Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for

3 x 0.023 FL. OZ. PACKAGE; 6 x 0.23 FL. OZ. PACKAGE)
3 x 0.045 FL. OZ. PACKAGE; 6 x 0.45 FL. OZ. PACKAGE)
3 x 0.091 FL. OZ. PACKAGE; 6 x 0.091 FL. OZ. PACKAGE)
3 x 0.136 FL. OZ. PACKAGE; 6 x 0.136 FL. OZ. PACKAGE)

(FRONT PANEL OF CARTON

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

[Alternate Brand Name]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENT:

Fipronil9.8%
(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))
(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))
(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))
(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

(0.13 fl. oz. (4.02 mL) (6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses))
(0.27 fl. oz. (8.04 mL) (6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses))
(0.546 fl. oz. (16.08 mL) (6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses))
(0.816 fl. oz. (24.12 mL) (6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses))

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-metoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

(BACK PANEL OF CARTON)

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies 5-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

[Alternate brand name]

[EPA Reg. No. 88052-xxx]

Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), and Deer ticks (*Ixodes scapularis*) [which may carry Lyme disease]]
- [Rapidly eliminates infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills the vectors that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the [proven effective] [topical] fipronil plus (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of mites that cause sarcoptic mange]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Same formulation as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

(LABEL DIRECTIONS FOR PACKAGE INSERT)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENT:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 5 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

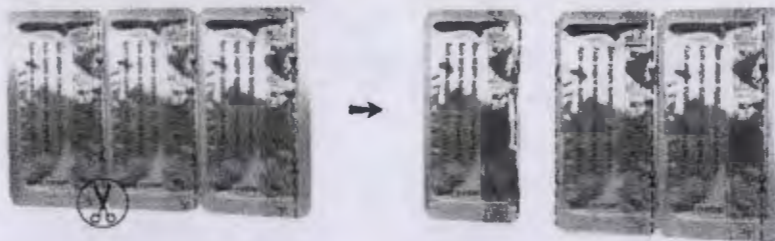
Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

To remove and open applicator:

- 1 Cut along scissor cut line to separate unit



- 2 Turn unit over and cut corner at bulb end



- 3 From cut corner, peel backing completely off from bottom to top



- 4 Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 5 to 132 lbs.

5-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses 0.13 fl. oz. (4.02 mL), 6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses 0.27 fl. oz. (8.04 mL), 6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses 0.546 fl. oz. (16.08 mL), 6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses 0.816 fl. oz. (24.12 mL), 6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

(Text for CRP Blister for

(TOP OF LIDDING FOIL—see back of blister: Dotted line with representation of a pair of scissors and two step directions to separate blisters)

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-xxxx

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 5-22 lbs. and 8 weeks or older

0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



(Text for Reminder Stickers for

[Optional marketing claims]

[Picture of Dog or Puppy]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

[Optional text with Company logo]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Company name and logo]

[Optional bar code]

21-Day Screen Completed by
Contractor

21-Day Expires on 10/19/12

Jacket # 88052-RG

MRID# 489558

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Stephen Schaible



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 05, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC
HORIZON VALLEY GENERICS, INC
4110 136TH ST. NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 28-SEP-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Completion of 21-Day Content Screen

PM- 10

EPA Reg. # (File Symbol) 88052-RG

Decision # D 470216

Data package delivered to
you on 10/12/12.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you, *SH*

Registration Division's 21-Day Content Team

Memorandum

Date: 10 / 10 / 12

To: PT110, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 9-28-12^{3/23/09}
 Experts In-Processing Signature: B.B. Date 10-2-12 Fee Paid: Yes ☒
 Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88052-RC</u>		EPA Receipt Date: <u>9-28-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)			yes X	no 	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes 	no 	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)			yes X	no 	
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * A.I. + % Composition added.
- Application issue: Product name on 857034 not consistent with product name being registered.
- * Registrant contacted. Issue resolved.
- * Data package approved.
- * CSF approved for non-food use.
- * Label approved.

NRID 489558

S-4813

AB

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbnpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAi).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAi	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✗				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAi	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility	✓					
830.6317	Storage stability		✗				
830.6319	Miscibility		✓				
830.6320	Corrosion Characteristics		✗				
830.6321	Dielectric Breakdown Voltage		✓				
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)			✓	
870.1200	Acute Dermal (LD50)			✓	
870.1300	Acute Inhalation (LC50)			✓	
870.2400	Acute Eye Irritation			✓	
870.2500	Acute Dermal Irritation			✓	
870.2600	Dermal Sensitization			✓	

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 1, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-470216
EPA File Symbol or Registration Number: 88052-RG
Product Name: C668.2 FOR DOGS
EPA Receipt Date: 28-Sep-2012
EPA Company Number: 88052
Company Name: HORIZON VALLEY GENERICS, INC

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC
HORIZON VALLEY GENERICS, INC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,
Peresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{924552&~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S- 924552

EPA File Symbol/Reg. No.

88052-RG

Pin-Punch Date:

9/28/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A310

Granted: A310

Amount Due: \$ 4307

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: S. Hill

Date: 10/1/12

Remarks:

Ross Gilbert

From: Arianna Shorey
Sent: Thursday, September 27, 2012 12:47 PM
To: Ross Gilbert
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

-----Original Message-----

From: paygovadmin@mail.doc.twai.gov [<mailto:paygovadmin@mail.doc.twai.gov>]
Sent: Thursday, September 27, 2012 10:55 AM
To: Arianna Shorey
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

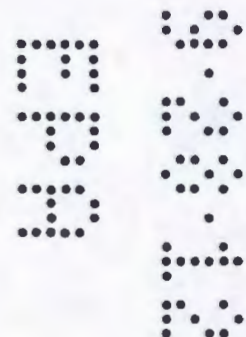
Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

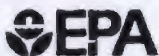
Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2584DEHG
Agency Tracking ID: 74361256497
Transaction Type: Sale
Transaction Date: Sep 27, 2012 1:55:06 PM

Account Holder Name: Ann Tillman
Transaction Amount: \$4,807.00
Billing Address: 4110 136th St NW
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98332
Country: USA
Card Type: AmericanExpress
Card Number: *****1031

Decision Number:
Registration Number:
Company Name: Horizon Valley Generics
Company Number: 88052
Action Code: R310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Horizon Valley Generics Inc./88052	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Horizon Valley Generics Inc./C668.2 for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Horizon Valley Generics Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-5 Product Name Frontline Plus for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R310 because it is an application for registration of a new end use product. The fee due which has been paid is \$4807 with a PRIA decision time line of 6 months.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136	No. per container 3	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.069, 0.136, 0.273, 0.408 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other on box and on inside box			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
Signature <i>Ann M Tillman</i>	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 9/27/12	

PYX REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

September 27, 2012

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Horizon Valley Generics, Inc.
C668.2 for Dogs (EPA File Symbol 88052-)
Application for New Pesticide Registration
PRIA Category R310

Dear Mr. Gebken,

On behalf of Horizon Valley Generics, Inc., we are submitting an application for registration of C668.2 for Dogs, an end use product containing the active ingredients fipronil and S-methoprene.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling for C668.2 for Dogs
4. A CD containing an electronic version of the label
5. Certification with Respect to Label Integrity
6. Agency Internal Use Copy of the Data Matrix
7. Public File Copy of the Data Matrix
8. Certification with Respect to Citation of Data (EPA Form 8570-34)
9. Formulator's Exemption Statement (EPA Form 8570-27)
10. Child Resistant Packaging Certifications
11. Copy of the PRIA payment from pay.gov
12. Letter of Authorization
13. Letter of authorization from sponsor of CRP testing
14. Product Specific Data (3 copies each):

Volume 1	830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for C668.2 for Dogs. <i>Contains Confidential Business Information.</i>
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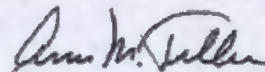
Volume 2	830.1800	Patel, A. H. Validation of Analytical Method for Active Ingredient Analysis of C668.2 by HPLC.
Volume 3	Group B 830 Series	Tillman, A. M. Self-Certification of Physical/Chemical Properties for C668.2 for Dogs.
Volume 4	830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7520	Tillman, A. M. Waiver Requests for Physical and Chemical Properties for C668.2 for Dogs.

Horizon Valley Generics, Inc. is using the cite-all method of data support for product specific data. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, Horizon Valley Generics, Inc. submitted notices of intent to apply and offers to pay to all companies on the March 29, 2012 Data Submitter's List or fipronil and S-methoprene. Horizon Valley Generic, Inc.'s C668.2 for Dogs qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements.

Horizon Valley Generics, Inc. believes this application falls under Category R310 (46: New end use product). The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months.

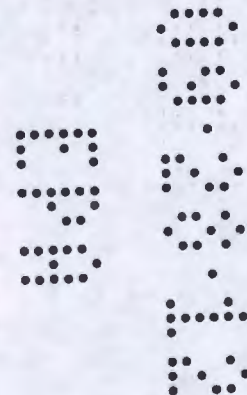
We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures





KLOCKE VERPACKUNGS-SERVICE GMBH

Klocke Verpackungs-Service GmbH Postfach 1140 D-76352 Weingarten

Horizon Valley Generics, Inc.
c/o Stinson Morrison Hecker LLP
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106
U.S.A.

Phone-No.: +33 3 88 45 33 13
Fax: +33 3 88 45 33 11
EMail-adress: richard.schwemmer@klocke.com

Contact: Richard SCHWEMMER

Date: 15.06.2011

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Letter of Authorization

Dear Madam, Dear Sir,

Please let this letter serve to notify you that **Horizon Valley Generics Inc.** (EPA Company number 88052) is authorized to submit the following CRP data in support of its application for registration of **HVG-D1, HVG-C, HVG-D2**, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.:

CITATION
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL Capacity. Report No. KVS-201101.
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.67 mL Capacity. Report No. KVS-201102.
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 1.34 mL Capacity. Report No. KVS-201103.
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 2.67 mL Capacity. Report No. KVS-201104.
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 4.02 mL Capacity. Report No. KVS-201105.

Klocke Verpackungs-Service GmbH owns the above listed data and submission by **Horizon Valley Generics Inc.** does not confer ownership rights of these data; other companies may rely on these data without compensation to **Horizon Valley Generics Inc.**

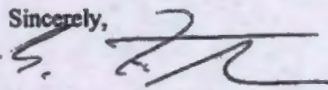
Please feel free to contact me should there be any questions.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 8
D-76352 Weingarten
Fax: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bankverbindungen:
HypoVereinsbank Karlsruhe, BLZ 66020286, Kto.-Nr. 352955442
IBAN: DE81660202860362955442, SWIFT (BIC): HYVEDE3333
Volksbank Weingarten-Walzachtal eG, BLZ 69061724, Kto.-Nr. 30218000
IBAN: DE03690617240030218000, SWIFT (BIC): GENODE33WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE900501010004022675, SWIFT (BIC): SOLADEST
Banque Paribas

Geschäftsführer: Carsten Klocke
Erfüllungsort: Weingarten/Baden
Gerichtsstand Karlsruhe
Registergericht: Amtsgericht
Mannheim HRB 105401
Ust-Id-Nr.: DE143584364
Steuer-Nr.: 34423/20401

Sincerely,



Mr Magnus ZUTHER
C.E.O.

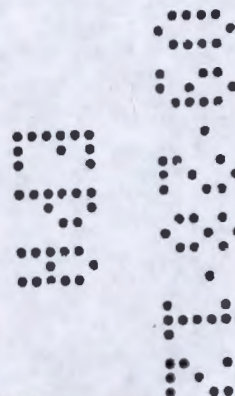
Klocke Verpackungs-Service GmbH
Max-Becker Strasse n° 6
D-76256 Weingarten
Germany

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/51-0
Fax: 07244/51-1170
Internet: www.klocke.com

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IBAN: DE81660202860362955442, SWIFT (BIC): HYVEDEMM475
Volksbank Weingarten-Walzachtal eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE31WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE90600501010004022675, SWIFT (BIC): SOLADEST
Banque Palatine

Geschäftsführer: Carsten Klocke
Erfüllungsort: Weingarten/Baden
Gerichtsstand Karlsruhe
Registergericht: Amtsgericht
Mannheim HRB 105401
Ust-Id-Nr.: DE143564364
Steuer-Nr.: 34423/20401





Horizon Valley Generics, Inc.

December 17, 2010

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

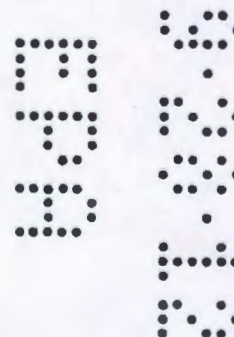
Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Horizon Valley Generics, Inc (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Bénédicte Deminière
CEO

cc: Pyxis Regulatory Consulting, Inc.



**Child Resistant Packaging Certification
For Horizon Valley Generic, Inc.'s 668.2 for Dogs
(EPA Registration No. 88052-)**

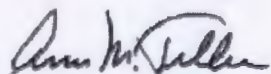
Registrant: Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 88052-[pending], C668.2 for Dogs is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has four fill levels, which are 0.023 fl. oz. (0.67 mL), 0.045 fl. oz. (1.34 mL), 0.091 fl. oz. (2.68 mL) and 0.136 fl. oz. (4.02 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at each of the four fill levels:

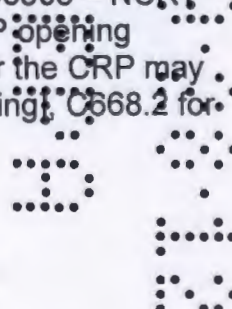
- 0.023 fl. oz. (0.67 mL) (MRID 48703501 – NCRT Child study no. 10-030 and NCRT Senior 11-044),
- 0.045 fl. oz. (1.34 mL) (MRID 48703502 – NCRT Child study no. 10-032 and NCRT Senior 11-045),
- 0.091 fl. oz. (2.68 mL) (MRID 48652701 – NCRT Child study no. 10-034 and NCRT Senior 11-046):
- 0.136 fl. oz. (4.02 mL) (MRID 48703503 – NCRT Child study no. 10-036 and NCRT Senior 11-047).

I realize that additional CRP testing may be required if EPA Registration No. 88052-[pending], C668.2 for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH on the same equipment as the samples tested** (0.023 fl. oz. (0.67 mL) (MRID 48703501 – NCRT Child study no. 10-030 and NCRT Senior 11-044), 0.045 fl. oz. (1.34 mL) (MRID 48703502 – NCRT Child study no. 10-032 and NCRT Senior 11-045), 0.091 fl. oz. (2.68 mL) (MRID 48652701 – NCRT Child study no. 10-034 and NCRT Senior 11-046): 0.136 fl. oz. (4.02 mL) (MRID 48703503 – NCRT Child 10-036 and NCRT Senior 11-047)). Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 88052-[pending], C668.2 for Dogs.



Ann M. Tillman
Agent for Horizon Valley Generics, Inc.
Pyxis Regulatory Consulting, Inc.

Sept. 27, 2012
Date





United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106	EPA File Symbol/Registration Number 88052-
	Product Name C668.2 for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/14/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil
S-Methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil		
S-Methoprene		
Signature 	Name and Title Ann M. Tillman, Agent	Date 9/27/12

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Horizon Valley Generics c/o Pyxis Regulatory Consulting Inc., 4110 136th St NW, Gig Harbor WA (253) 853-7369	EPA Registration Number/File Symbol 88052-
Active Ingredient(s) and/or representative test compound(s) Fipronil, S-Methoprene	Date 9/27/12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor	Product Name C668.2 for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

Date

9/27/12

Typed or Printed Name and Title

Ann M. Tillman, Agent

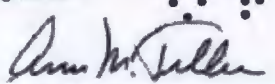
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DATA MATRIX

Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 1 of 9	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1800	Enforcement Analytical Method	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.6302	Color	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.6303	Physical State	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.6304	Odor	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.6315	Flammability	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.6316	Explosibility	Volumes 3, 4	Horizon Valley Generics, Inc.	OWN	Waiver ⁴
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

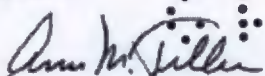
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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	Volumes 3, 4	Horizon Valley Generics, Inc.	OWN	PR-92-5 ⁵
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	Volumes 3, 4	Horizon Valley Generics, Inc.	OWN	PRN 92-53 ⁵
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.7050	UV/Visible Absorption				Not Required ⁸
830.7100	Viscosity	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.7200	Melting Point/Melting Range				Not Required ⁸
830.7220	Boiling Point/Boiling Range				Not Required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 3	Horizon Valley Generics, Inc.	OWN	
830.7370	Dissociation Constants in Water				Not Required ⁸
830.7520	Particle size, fiber length, diameter distribution	Volume 4	Horizon Valley Generics, Inc.	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

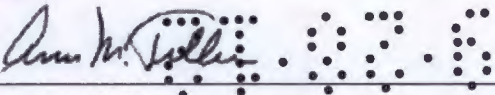
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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ⁸
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
870.7200	Companion Animal Safety	Cite-All		PAY	
810.3300	Product Performance	Cite-all		PAY	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012	


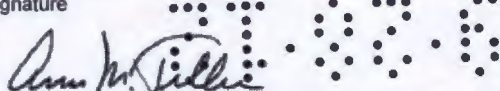
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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study	48703501	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	See endnote ¹⁰
		48703502	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
		48652701	Horizon Valley Generics, Inc.	PER	
		48703503	Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
Generic Data Requirements					
Horizon Valley Generic, Inc.'s C668.2 for Dogs qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements.					
Product Specific Data Requirements					
Horizon Valley Generic, Inc. will make offers-to-pay to the following companies on the March 29, 2012 Data Submitters List for fipronil.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

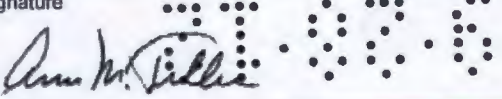
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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Pfizer, Inc.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Gharda Chemicals Limited	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

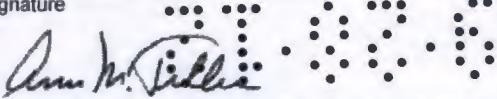
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012


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Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 7 of 9	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Norbrook, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Lnouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite - Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Tru Prodigy Animal Health, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

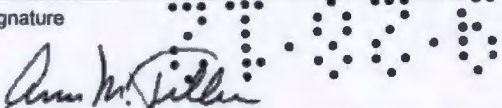
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 7 of 9	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
Horizon Valley Generic, Inc. will make offers-to-pay to the following companies on the March 29, 2012 Data Submitters List for S-methoprene.					
		Cite-All	ADM Alliance Nutrition, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Wellmark International	PAY	
		Cite-All	S. C. Johnson & Son Inc.	PAY	
		Cite-All	Chattem, Inc.	PAY	
		Cite-All	Zep Commercial Sales & Service	PAY	
		Cite-All	Control Solutions, Inc.	PAY	
		Cite-All	Management Contract Services, Inc.	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	B2E Corp.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

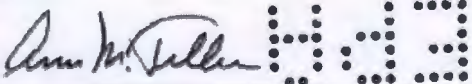
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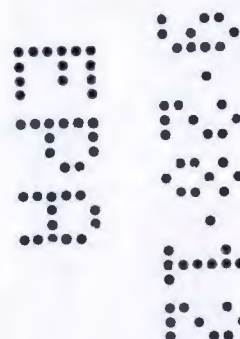
DATA MATRIX

Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 9 of 9	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Babolna Bioenvironmental Centre Ltd.	PAY	
		Cite-All	Egis Pharmaceuticals Public Limited Co.	PAY	
		Cite-All	Valent Biosciences Corp.	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Hartz-B2E LLC	PAY	
		Cite-All	B2E Biotech LLC	PAY	
		Cite-All	Zocor Inc.	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Envincio LLC	PAY	
		Cite-All	U.S. Animal Health	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

37.07.6

Endnotes for Data Matrix for C668.2 for Dogs

- ¹ **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** - This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** - These data are not required for registration of an end-use product.
- ⁴ **830.6316** - Neither the active ingredients, fipronil or S-methoprene, nor any of the inert ingredients in C668.2 for Dogs contains the chemical bonds or functional groups associated with chemicals that are explosive. Therefore, a waiver from this data requirement is requested.
- ⁵ **830.6317, 830.6320** -Per PR Notice 92-5, storage stability and corrosion characteristic data are not required to be submitted unless specifically requested by the Agency.
- ⁶ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. C668.2 for Dogs is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- ⁷ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- ⁸ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** - These data are not required for registration of an end-use product.
- ⁹ **830.7520** - Horizon Valley Generics Inc. is seeking a waiver for this data requirement for C668.2 for Dogs because the product is not a fibrous material or a water-insoluble material.
- ¹⁰ Although these data were submitted by Chanelle Pharmaceuticals Manufacturing Ltd., Horizon Valley Generics Inc. has permission to cite these data from the sponsor of the studies, Klocke Verpackungs-Service GMBH.



(Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for

3 x 0.023 FL. OZ. PACKAGE; 6 x 0.23 FL. OZ. PACKAGE)
3 x 0.045 FL. OZ. PACKAGE; 6 x 0.45 FL. OZ. PACKAGE)
3 x 0.091 FL. OZ. PACKAGE; 6 x 0.091 FL. OZ. PACKAGE)
3 x 0.136 FL. OZ. PACKAGE; 6 x 0.136 FL. OZ. PACKAGE)

(FRONT PANEL OF CARTON

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

[Alternate Brand Name]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENT:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))
(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))
(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))
(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

(0.13 fl. oz. (4.02 mL) (6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses))
(0.27 fl. oz. (8.04 mL) (6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses))
(0.546 fl. oz. (16.08 mL) (6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses))
(0.816 fl. oz. (24.12 mL) (6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses))

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

(BACK PANEL OF CARTON)

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

(Use **ONLY** on dogs and puppies 5-22 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)

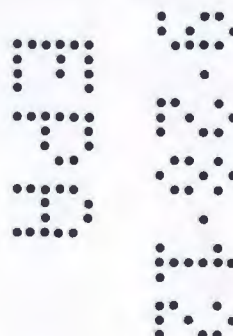
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)

[C668.2 for Dogs]

[Alternate brand name]

[EPA Reg. No. 88052-xxx]

Lot/Batch Number



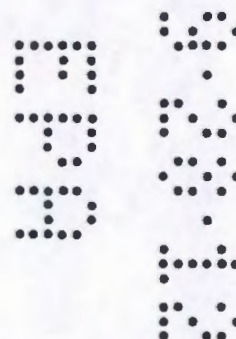
[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), and Deer ticks (*Ixodes scapularis*) [which may carry Lyme disease]]
- [Rapidly eliminates infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills the vectors that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the [proven effective] [topical] fipronil plus (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of mites that cause sarcoptic mange]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]



- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Same formulation as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]



(LABEL DIRECTIONS FOR PACKAGE INSERT)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENT:

Fipronil	9.8%
(S)-Methoprene.....	8.8
OTHER INGREDIENTS:	81.4%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 5 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

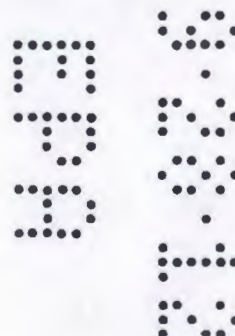
Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.



(LABEL DIRECTIONS FOR PACKAGE INSERT)

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 5 to 132 lbs.

5-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses 0.13 fl. oz. (4.02 mL), 6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses 0.27 fl. oz. (8.04 mL), 6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses 0.546 fl. oz. (16.08 mL), 6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses 0.816 fl. oz. (24.12 mL), 6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses

WARRANTY

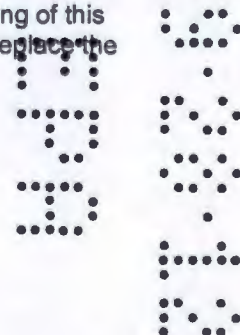
To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.



(Text for CRP Blister for

(TOP OF LIDDING FOIL—see back of blister: Dotted line with representation of a pair of scissors and two step directions to separate blisters)

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-xxxx

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 5-22 lbs. and 8 weeks or older

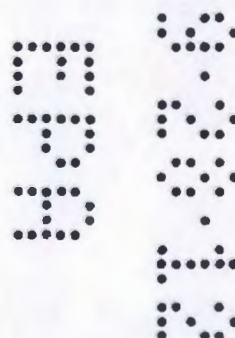
0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

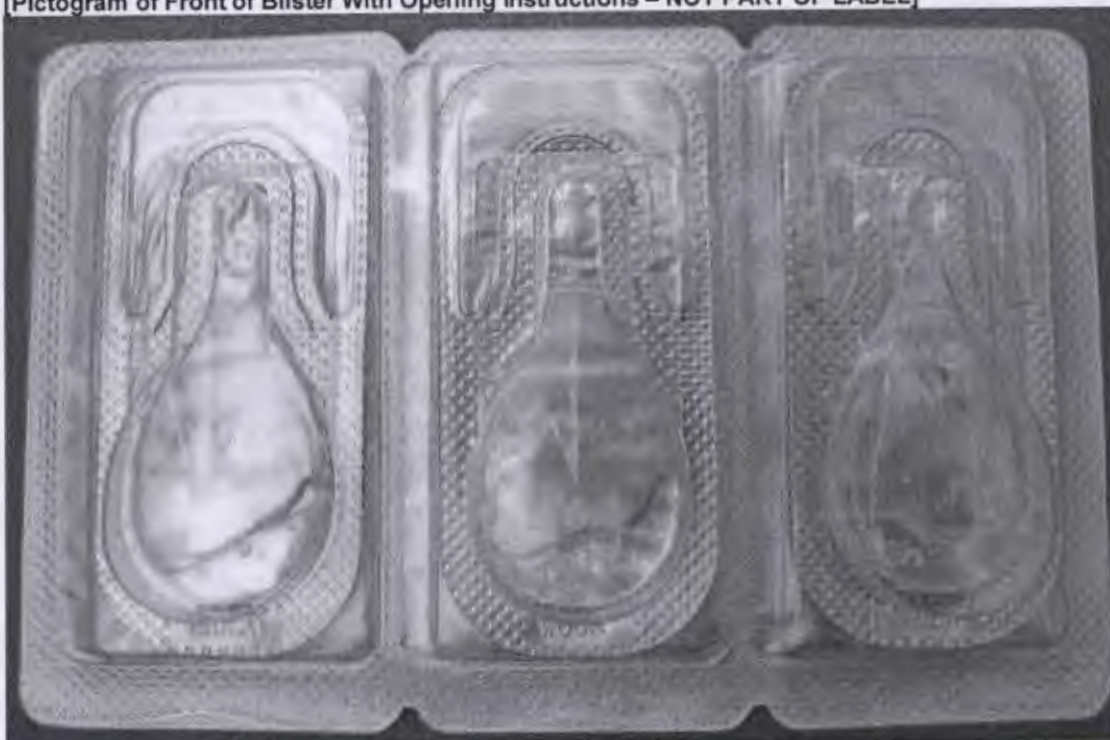
0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

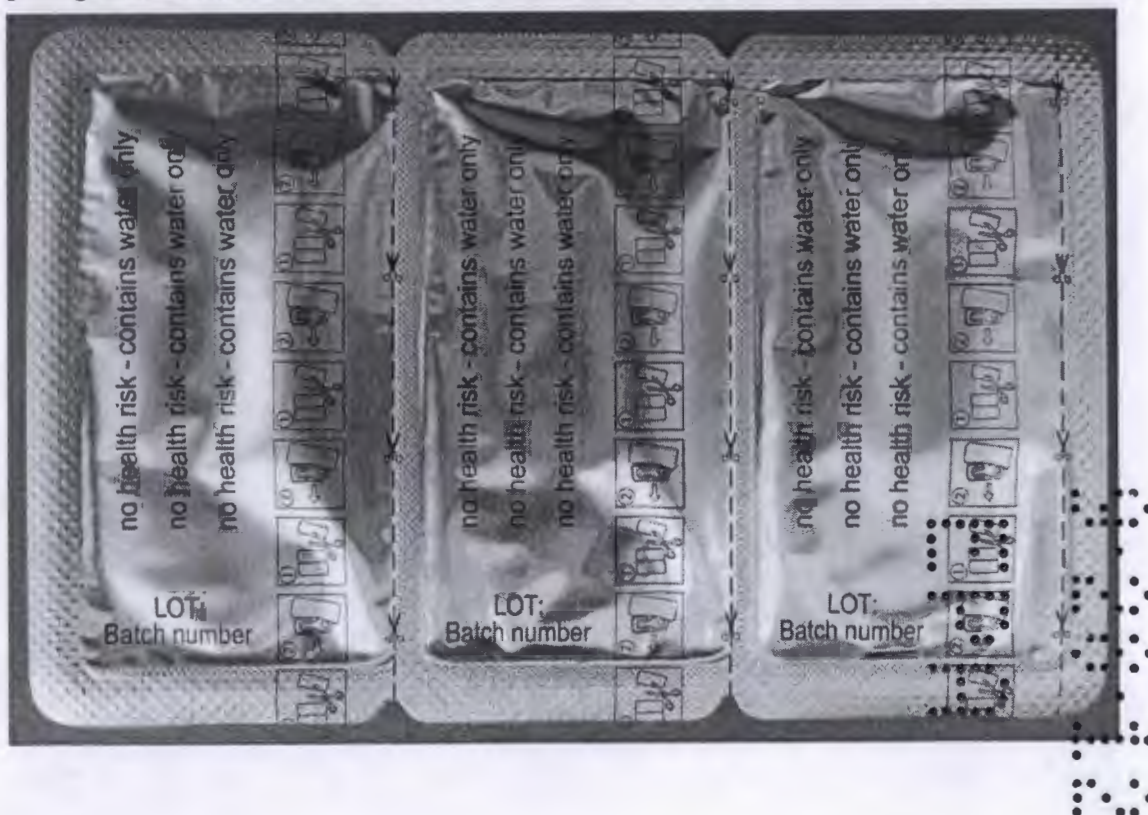
(S)-Methoprene 8.8%



[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



(Text for Reminder Stickers for

[Optional marketing claims]

[Picture of Dog or Puppy]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

[Optional text with Company logo]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

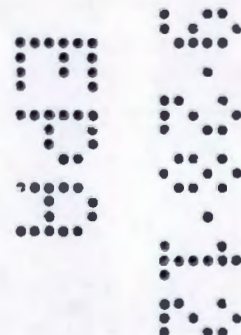
For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Company name and logo]

[Optional bar code]



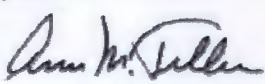
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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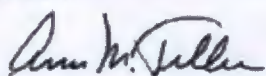
DATA MATRIX

Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 1 of 9	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C668.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not required ¹
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not Required ²
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
					Not Required ³
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	
			Horizon Valley Generics, Inc.	OWN	Waiver ⁴
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C668.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Horizon Valley Generics, Inc.	OWN	PR-92-5 ⁵
					Not required ⁶
			Horizon Valley Generics, Inc.	OWN	PRN 92-53 ⁵
					Not required ⁷
			Horizon Valley Generics, Inc.	OWN	
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	
					Not Required ⁸
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	
					Not Required ⁸
			Horizon Valley Generics, Inc.	OWN	Waiver ⁹
		Not Required ⁸			
					See 830.7560
					See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106	Product C668.2 for Dogs	

Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not Required ⁸
					See 830.7840
					Not Required ⁸
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	

Ann M. Tiller

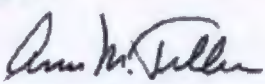
Ann M. Tillman, Consultant

Sept. 27, 2012

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WASHINGTON, D.C. 20460

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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Chanelle Pharmaceuticals Manufacturing Ltd.	PER	See endnote ¹⁰
			Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
			Horizon Valley Generics, Inc.	PER	
			Chanelle Pharmaceuticals Manufacturing Ltd.	PER	
			Syngenta Crop Protection LLC	PAY	
			The Scotts Company	PAY	
			Bayer Cropscience LP	PAY	
			Bayer Environmental Science	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

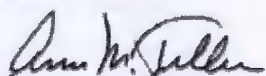
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DATA MATRIX

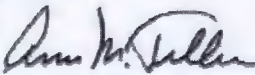
Date September 27, 2012			EPA Reg. No./File Symbol 88052-		Page 5 of 9
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C668.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Whitmire Micro-Gen Research Laboratories	PAY	
			Pfizer, Inc.	PAY	
			Virbac AH, Inc.	PAY	
			Sergeant's Pet Care Products, Inc.	PAY	
			The Hartz Mountain Corp.	PAY	
			Reckitt Benckiser LLC	PAY	
			Cheminova A/S	PAY	
			J. J. Mauget Co.	PAY	
			BASF Corp.	PAY	
			Chemsico	PAY	
			Makhteshim Chemical Works Ltd.	PAY	
			Gharda Chemicals Limited	PAY	
			Control Solutions Inc.	PAY	
			Virbac	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Combat Insect Control Systems	PAY	
			Pyrethroid Working Group	PAY	
			Merial Limited	PAY	
			Spray Drift Task Force	PAY	
			Cheminova Inc.	PAY	
			Outdoor Residential Exposure Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Ambrands	PAY	
			Innovative Pest Control Products	PAY	
			FIFRA Endangered Species Task Force	PAY	
			Irivita Plant Protection	PAY	
			Residential Exposure Joint Venture	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

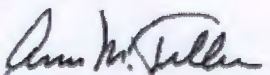
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Agricultural Handlers Exposure Task Force	PAY	
			Sharda USA LLC	PAY	
			Fidopharm, Inc.	PAY	
			Norbrook, Inc.	PAY	
			Loradochem, Inc.	PAY	
			Lnouvel, Inc.	PAY	
			Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
			Argite - Fipronil LLC	PAY	
			Firponex Solutions Inc.	PAY	
			Virbac S. A.	PAY	
			Raymat Materials Inc.	PAY	
			Chanelle Pharmaceuticals Manufacturing	PAY	
			Tru Prodigy Animal Health, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

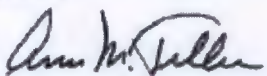
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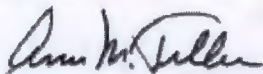
Date September 27, 2012		EPA Reg. No./File Symbol 88052-		Page 8 of 9	
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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ADM Alliance Nutrition, Inc.	PAY	
			Sergeant's Pet Care Products, Inc.	PAY	
			The Hartz Mountain Corp.	PAY	
			Wellmark International	PAY	
			S. C. Johnson & Son Inc.	PAY	
			Chatterm, Inc.	PAY	
			Zep Commercial Sales & Service	PAY	
			Control Solutions, Inc.	PAY	
			Management Contract Services, Inc.	PAY	
			Merial Limited	PAY	
			Spray Drift Task Force	PAY	
			B2E Corp.	PAY	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012	

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Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Babolna Bioenvironmental Centre Ltd.	PAY	
			Egis Pharmaceuticals Public Limited Co.	PAY	
			Valent Biosciences Corp.	PAY	
			Ambrands	PAY	
			Hartz-B2E LLC	PAY	
			B2E Biotech LLC	PAY	
			Zocor Inc.	PAY	
			Fidopharm, Inc.	PAY	
			Loradochem, Inc.	PAY	
			Envincio LLC	PAY	
			U.S. Animal Health	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2012

21.02.0

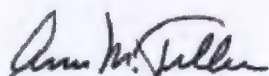
Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

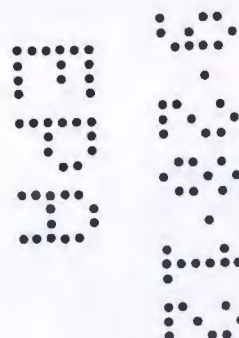
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088052-xxxxxx	Sept. 27, 2012	088052-xxxxxx.20120927.C668.2 for Dogs label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent for Horizon Valley Generics, Inc.

Sept. 27, 2012
Date



There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Rena Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

PROCESSING ELECTRO C LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

¹ ITRMD receives paper submission w/ e-label on CD

² Tracking record added to OPPIN

³ ITRMD adds e-label to ELL

⁴ ITRMD sends paper submission to AD/BPPD/RD

⁵ Connect ELL record with OPPIN S#

in-process

⁶ Save copy of e-label from ELL to My Documents

⁷ Review label
(if acceptable, skip to step 20)

⁸ Add comments to e-label
(save; add "with comments" to filename)

⁹ Print annotated e-label
(use "Print with Filename")

review

¹⁰ Send annotated e-label to registrant via email
(also send "How To Print")

¹¹ File print of annotated e-label and email in jacket

¹² Add annotated e-label to ELL

¹³ Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

¹⁴ Receive email submission w/ e-label attached

¹⁵ Add tracking record to OPPIN

¹⁶ Add e-label to ELL

¹⁷ Connect ELL record with OPPIN S#

in-process

¹⁸ Save copy of e-labels (old & new) from ELL to My Documents

¹⁹ Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

²⁰ Print e-label, stamp, write cover letter
(use "Print with Filename")

²¹ Mail stamped label & cover letter to registrant

²² File stamped label & cover letter in jacket

²³ Add cover letter to ELL
(mandatory if accepted with comments)

²⁴ Close submission in OPPIN

out-process

process - big picture

- 1- create OPPIN tracking
- 2- put label in ELL; link to S#
- 3- save ELL label to MyDocuments
- 4- compare / comment
- 5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

(Label Directions and Container (Carton), Package Insert, Blister, and Reminder
Stickers for

3 x 0.023 FL. OZ. PACKAGE; 6 x 0.23 FL. OZ. PACKAGE)
3 x 0.045 FL. OZ. PACKAGE; 6 x 0.45 FL. OZ. PACKAGE)
3 x 0.091 FL. OZ. PACKAGE; 6 x 0.091 FL. OZ. PACKAGE)
3 x 0.136 FL. OZ. PACKAGE; 6 x 0.136 FL. OZ. PACKAGE)

(FRONT PANEL OF CARTON

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

[Alternate Brand Name]

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

ACTIVE INGREDIENT:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

(0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))
(0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))
(0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))
(0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

(0.13 fl. oz. (4.02 mL) (6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses))
(0.27 fl. oz. (8.04 mL) (6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses))
(0.546 fl. oz. (16.08 mL) (6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses))
(0.816 fl. oz. (24.12 mL) (6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses))

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

Manufactured for:
Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany
C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
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QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

(BACK PANEL OF CARTON)

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

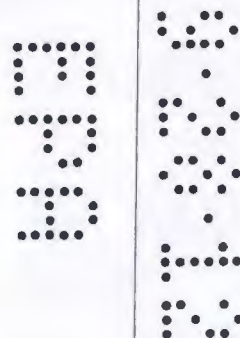
Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(SIDE PANELS OF CARTON)

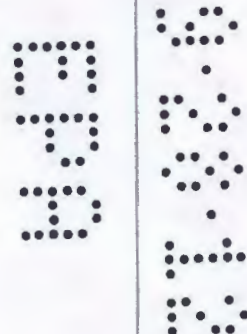
(Use **ONLY** on dogs and puppies 5-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)
[C668.2 for Dogs]
[Alternate brand name]
[EPA Reg. No. 88052-xxx]
Lot/Batch Number



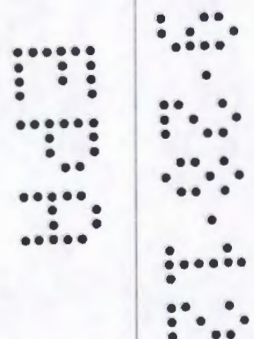
[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), and Deer ticks (*Ixodes scapularis*) [which may carry Lyme disease]]
- [Rapidly eliminates infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills the vectors that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the [proven effective] [topical] fipronil plus (S)-methoprene found in Frontline® Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Kills mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of mites that cause sarcoptic mange]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]



- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Same formulation as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]



(LABEL DIRECTIONS FOR PACKAGE INSERT)

C668.2 FOR DOGS

(Use **ONLY** on dogs and puppies weighing 5-22 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease
Aids in control of sarcoptic mange mite infestations.

ACTIVE INGREDIENT:

Fipronil9.8%

(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 5 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

SIDE EFFECTS

Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

DIRECTIONS FOR USE

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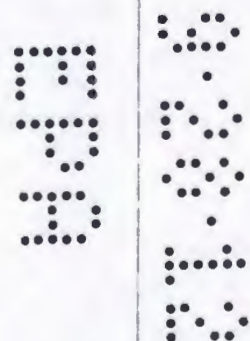
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C668.2 FOR DOGS

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Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 5 pounds.

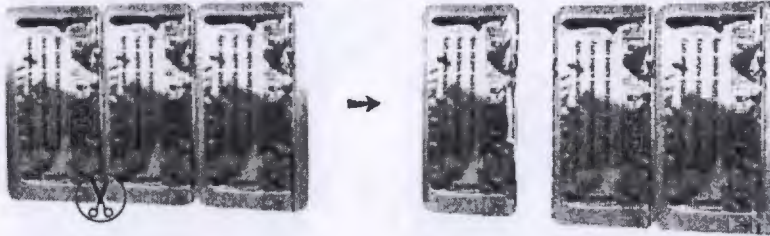
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(LABEL DIRECTIONS FOR PACKAGE INSERT)

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[PICTOGRAM ON HOW TO APPLY]

To apply C668.2 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

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Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations. To eliminate mites, apply C668.2 for Dogs every 30 days.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

CAT PROHIBITION ICON

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 5 to 132 lbs.

5-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses 0.13 fl. oz. (4.02 mL), 6 applicators each containing 0.023 fl. oz. (0.67 mL); 6 Doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses 0.27 fl. oz. (8.04 mL), 6 applicators each containing 0.045 fl. oz. (1.34 mL); 6 Doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses 0.546 fl. oz. (16.08 mL), 6 applicators each containing 0.091 fl. oz. (2.68 mL); 6 Doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 doses 0.816 fl. oz. (24.12 mL), 6 applicators each containing 0.136 fl. oz. (4.02 mL); 6 Doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

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(Text for CRP Blister for

(TOP OF LIDDING FOIL—see back of blister: Dotted line with representation of a pair of scissors and two step directions to separate blisters)

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C668.2 for Dogs

EPA Reg. No. 88052-xxxx

Lot/Batch No.

CAT PROHIBITION ICON

0.023 fl. oz. - Only for Dogs & Puppies 5-22 lbs. and 8 weeks or older

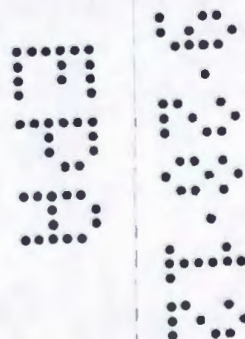
0.045 fl. oz. - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older

0.091 fl. oz. Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older

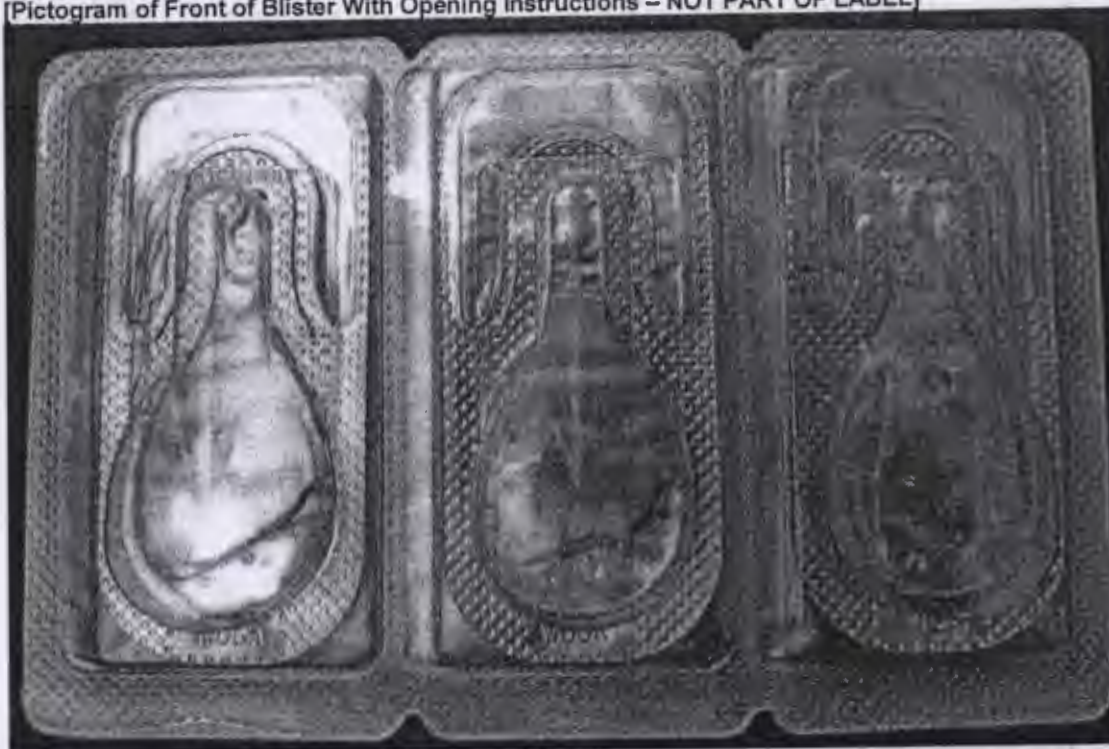
0.136 fl. oz. Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 8.8%



[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



(Text for Reminder Stickers for

[Optional marketing claims]

[Picture of Dog or Puppy]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

[Optional text with Company logo]

C668.2 for Dogs

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[Company name and logo]

[Optional bar code]

